

CLASS

Summary of the CLASS Trial Comparison of LAser, Surgery and foam Sclerotherapy

We are conducting a study to find out which treatment is best for patients who have varicose veins. We understand that you have been referred to the hospital about your varicose veins. You might be eligible to take part in our study, and we would be grateful if you would consider taking part.

In our study, we are comparing three different treatments. All of the treatments get rid of varicose veins in the short term but have their own advantages and disadvantages.

In our study, we will compare how well each treatment works in getting rid of varicose veins and in improving the quality of life of patients. We will also look at the recovery and side effects of the treatments and their "value for money".

Standard surgical treatment - removal of the veins under general anaesthetic

Laser treatment - laser treatment to the veins which causes them to close off and shrivel up

Foam sclerotherapy - injections into the veins which causes them to close off and shrivel up

We are inviting patients to take part in this study. Patients who agree will:

- be asked to sign a consent form;
- be allocated to receive one of these treatments by chance;
- have the treatment they have been allocated to;
- be asked to complete questionnaires when they join the study, six weeks after their treatment, six months after their treatment and then every year for five years
- be invited to a follow-up clinic visit six weeks, six months and five years after their treatment (travel expenses will be available to cover the cost of coming to these appointments).

By taking part in the study, patients will give up the right to choose which treatment they receive.

If you are interested in finding out more about the study, the surgeon will tell you about it when you come to your hospital appointment. At this appointment we will give you an information leaflet about the study and one about varicose veins and the different treatments. In the meantime, you can call us on the number above if you would like any more information sent to you.

If you do not want to take part in the study, please tell the surgeon when you come to your hospital appointment.

Thank you

Patients and doctors rely increasingly on the results of studies like this to make sure they are making the right decisions about treatment.

Thank you for reading this leaflet. We hope it was useful in helping you to decide whether or not you would like to help us by participating in this study.

CLASS

Summary of the CLASS Trial Comparison of LAser, Surgery and foam Sclerotherapy

We are conducting a study to find out which treatment is best for patients who have varicose veins. We would be grateful if you would consider taking part in this study.

In our study, we are comparing three different treatments. All of the treatments get rid of varicose veins in the short term but have their own advantages and disadvantages.

In our study, we will compare how well each treatment works in getting rid of varicose veins and in improving the quality of life of patients. We will also look at the recovery and side effects of the treatments and their "value for money".

Standard surgical treatment - removal of the veins under general anaesthetic

Laser treatment - laser treatment to the veins which causes them to close off and shrivel up

Foam sclerotherapy - injections into the veins which causes them to close off and shrivel up

We are inviting patients to take part in this study. Patients who agree will be:

- Asked to sign a consent form;
- Allocated to receive one of these treatments by chance;
- Have the treatment they have been allocated to;
- Asked to complete questionnaires when they join the study, six weeks after their treatment, six months after their treatment and then every year for five years
- Invited to a follow-up clinic visit six weeks, six months and five years after their treatment (travel expenses will be available to cover the cost of coming to these appointments).

By taking part in the study, patients will give up the right to choose which treatment they receive. They will be told which treatment they have been allocated to receive about two weeks before their treatment.

You can read more about varicose veins, the different treatments, and about this study in the patient information leaflets.

Thank you

Patients and doctors rely increasingly on the results of studies like this to make sure they are making the right decisions about treatment.

Thank you for reading this leaflet. We hope it was useful in helping you to decide whether or not you would like to help us by participating in this study.

CLASS

Comparison of LAser, Surgery and foam Sclerotherapy

PATIENT STUDY INFORMATION LEAFLET

BOOKLET 1

You are invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read this information leaflet carefully and discuss it with others, if you wish. Please ask us if there is anything that is not clear, or if you would like more information. Take as much time as you need to decide whether or not you want to take part.

What is the purpose of the study? The purpose of this study is to find out which treatment is best for patients who have varicose veins. We will do this by treating patients who agree to take part with either the standard treatment that is surgery, or alternatively newer treatments which are foam sclerotherapy alone or laser treatment and foam sclerotherapy. These treatments are described below and in more detail in the leaflet “Varicose veins and treatment” which you have been given. We will compare the treatments to find out which is better for getting rid of varicose veins and improving your general health and well-being (quality of life). Patients will be allocated by chance to one of the treatments using a process which is similar to tossing a coin.

More about varicose veins: Varicose veins are veins under the skin of the legs that have become widened, bulging and twisted. They are very common and do not cause medical problems in most people. They may cause aching, discomfort, and heaviness of the legs, which are usually worse at the end of the day. Sometimes the ankle can swell, too. Varicose veins in some cases may occasionally become red and painful or bleed. In a few patients they may lead to skin rashes, a brown discolouration of the skin around the ankle or a break in the skin.

More about standard surgical treatment: This involves removal of the varicose veins under a general anaesthetic. A small cut is then made in the crease of the groin or behind the knee. The main vein is tied off just where it joins the deep vein. This vein is removed by passing a fine wire down it and removed through a small incision further down the leg. Varicose veins marked before the operation are removed through tiny cuts.

Possible advantages and disadvantages of standard surgery

- Standard surgery removes all the varicose veins at a single procedure. It should not be necessary to have anything more done to get rid of any remaining varicose veins.
- Varicose vein surgery is normally done under a general anaesthetic.
- Bruising is common. People with smaller varicose veins may get very little bruising but people with big varicose veins may be very bruised. All the bruising goes away.
- There may be some discomfort from the groin wound and occasionally the groin wound can become infected.
- You can become fully active as quickly as you want after standard surgery.
- Most surgeons advise wearing a support stocking for 10 days and avoiding getting the legs wet (in a bath or shower) during this time.
- Standard surgery gives a good long term result to many people but varicose veins may gradually reappear over the years.
- It is a tried and tested treatment which has been used for many years.
- In summary, surgical treatment involves a general anaesthetic, an incision in the groin or knee and often some bruising. However, all the varicose veins can be dealt with thoroughly by a single treatment, in one or both legs.

More about foam sclerotherapy: This involves injection of a fluid “sclerosant” which is mixed with a small quantity of air in the form of tiny bubbles. This causes the walls of the vein to glue together so that they close off and shrivel up. Foam sclerotherapy involves a number of injections into the veins of the leg and is done under local anaesthetic. These injections are carried out with the help of ultrasound pictures to be sure that the tip of the needle is correctly positioned in the vein. More than one treatment session may be required, particularly for varicose veins on both legs and veins which are very extensive.

Possible advantages and disadvantages of foam sclerotherapy

- Foam sclerotherapy is done under local anaesthetic, but sometimes no anaesthetic is required at all.
- No surgical incisions are required.

- The veins which have been treated may remain lumpy, hard and sometimes tender for several weeks or even months.
- More than one treatment session may be required, particularly for varicose veins on both legs and for veins which are very extensive.
- You can become fully active as quickly as you want after foam sclerotherapy treatment.
- Bandages and a support stocking are put on the leg after foam sclerotherapy treatment, and need to be worn for 10 days. These must be kept dry.
- Varicose veins may gradually reappear in the years after foam sclerotherapy treatment: this is rather more likely than after surgery. They can be treated with further foam sclerotherapy if required.
- In summary, foam sclerotherapy is a simple treatment to have but firm compression from a support stocking is important afterwards. The treated veins may be hard and tender for some time and there may be some brown staining. Repeat treatment sessions may be needed, particularly if there are varicose veins in both legs. New veins may gradually appear.

More about laser treatment: Laser treatment uses heat to damage the walls of the vein causing them to glue together so that they close off and shrivel up. Using ultrasound pictures a special laser fibre is inserted into the vein through a tiny incision near the knee and is advanced up to the top of the vein in the groin. Local anaesthetic and cold fluid are injected around the vein. Pulses of laser light are then used to seal off the vein. Sometimes we may need to use a combination of laser treatment in the thigh and foam sclerotherapy around the knee or upper calf. If required, this will be done at the same treatment session. The veins further down the leg often shrink after laser treatment, but if they persist they can be treated by foam sclerotherapy. One hospital in this study will use phlebectomies (removal of varicose veins through tiny incisions) at the same time as laser treatment.

Possible advantages and disadvantages of laser treatment

- Laser treatment can be done under local anaesthetic, rather than general anaesthetic.
- No incision is needed in the groin.
- It avoids the bruising which can sometimes occur after standard surgery, but you may experience some lumpiness and tenderness in the thigh which can take several weeks to settle.
- Foam sclerotherapy or phlebectomies may be required to get rid of all the varicose veins. This may mean returning for treatment on another occasion.
- You can become fully active as quickly as you want after laser treatment.
- Most surgeons advise wearing a support stocking for 10 days and avoiding getting the legs wet (in a bath or shower).
- Laser treatment seems to give results as good as standard surgery up to five years but varicose veins may gradually reappear over the years.
- In summary, laser treatment can be done under local anaesthetic, requiring several injections into the thigh. Additional treatment may be needed to get rid of all the varicose veins.

Have any studies like this been done before? Yes, there are a number of studies that have shown that either foam sclerotherapy or laser treatment can get rid of varicose veins. However, these studies have not involved all three treatments and did not assess how well each treatment worked in the long-term. Currently we do not know what is the best treatment in terms of getting rid of veins, quality of life and value for money.

Why have I been chosen? You have been chosen because we believe that you are suitable for this study. You have varicose veins which may be treated by surgery, foam sclerotherapy or laser treatment.

Do I have to take part? No. It is entirely up to you to decide whether or not to take part. If you do decide to take part, please keep this information leaflet and the one on "Varicose veins and treatment". You will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part? If you agree to take part in the study, the study nurse will contact you by telephone in order to arrange a clinic appointment. At this appointment, you will undergo an ultrasound scan of your veins if you have not already had one. This scan involves placing jelly and a probe over the vein. It is painless and lasts up to 20 minutes. You will then be asked to sign a consent form and fill in a questionnaire. The nurse will be available to help with any queries you may have. If there is not enough time at the clinic or if you would prefer, you can complete the questionnaire at home.

You will undergo treatment of your varicose veins by either standard surgery, foam sclerotherapy or laser treatment usually within 4 months. You will be informed of what treatment you are due to receive and the date of this treatment at least two weeks before you are due to attend. At this stage you will be asked to fill in a short questionnaire which will be sent to your home. This questionnaire will let us know if your views on your varicose veins have changed since you agreed to take part in the study.

You will have 2 further clinical visits to the hospital clinic at 6 weeks and 6 months after treatment. You can receive travel expenses. At the clinic you will undergo an examination of your legs, an ultrasound scan and be asked to fill in a questionnaire. The nurse will be available to help with any queries you may have. Each clinic visit should take approximately 1 hour. If you require further treatment with foam sclerotherapy to any remaining varicose veins this will be carried out whenever possible at the same clinic appointment by a doctor.

We are seeking further funding to continue the study to 5 years following your treatment. Assuming we are successful, we will ask you to fill out a questionnaire each year. These will be sent to you by post. At 5 years following your treatment for varicose veins we will ask you to attend a clinic appointment in order to undergo an examination of your leg and an ultrasound scan.

If you agree to take part we will also ask for your permission to consult your medical records. This ensures that the information about you is correctly recorded in the study documentation.

What will I have to do? You will be asked to attend clinic appointments as described above. Your varicose veins will be treated using either standard surgical treatment, foam sclerotherapy or laser treatment.

What is the drug, device or procedure that is being tested? Foam sclerotherapy and laser treatment are being compared with standard surgery. Both of these new treatments are being increasingly used in the NHS and are approved by the National Institute for Health and Clinical Excellence (NICE).

What are the possible disadvantages and risks of taking part? By taking part in the study you will give up your right to choose which treatment you receive. You will be allocated to receive one of the treatments by chance. You will also be given less notice of which treatment you will undergo. We will tell you which treatment you are due to receive about two weeks before your treatment. Your treatment however will not be delayed by your decision to take part in the study. There is a common waiting list for all patients with varicose veins whether they are taking part in the study or not.

There are potential disadvantages/risks of all three treatments. All three treatments for varicose veins are associated with a low risk of developing a clot in the deep veins of the leg known as a deep vein thrombosis. Rarely, a clot like this may break up and travel to the lungs. Varicose veins may come back in the future. The main risks of each treatment are summarised below. For more details please read the leaflet on "Varicose veins and treatment". This gives information on rare but important complications that may occur.

Surgery: You may experience discomfort following surgery. It is common for the area under the wound in the groin or behind the knee to feel tender for a few days and thickened for a few weeks. Bruising is common, and will settle. Infection is an occasional problem,

particularly in groin wounds. The scars on your legs are easily noticeable to start with, but will continue to fade for many months after the operation. Very occasionally, some people develop a little brown staining where the veins were removed, or the appearance of tiny red or blue veins. Nerves under the skin can be damaged when removing varicose veins close to them and small areas of numbness are quite common. The risk of a deep vein thrombosis following surgery is about 1% (1 in 100). Very rarely the main artery, vein or nerve in your leg may be damaged.

Many people develop a few new varicose veins during the years after a varicose vein operation. Five years after operation about one person in eight has troublesome varicose veins again.

Foam sclerotherapy: You may experience discomfort following the injection of foam. The veins which have been treated may remain lumpy, hard and sometimes tender for several weeks. Skin staining over the veins may occur but will fade with time. Rarely, the skin at the injection site may break down and require treatment. Very occasionally, some people develop tiny red or blue veins. The risk of a deep vein thrombosis following foam injections is about 1% (1 in 100). Some patients experience some temporary confusion after foam treatment – but this generally lasts only a few minutes. There is a small risk that you may experience a brief (about 30 minutes) period of disturbed vision (blurred vision or loss of vision) – the risk is 1% (1 in 100), no permanent damage to eye sight has been reported. Occasionally, people report headache, or migraine-like symptoms after foam sclerotherapy. There is a very small risk of a stroke following foam treatment. All the surgeons involved in this study take care to limit the amount of foam that is used at any one time and this minimises the risk. That is the reason that we often treat only one leg at a time, even if both legs are to be treated. Worldwide, three patients have been reported as having foam injected into an artery rather than a vein. One patient has had a fit following foam, but it is unclear if this was related to the treatment. A severe allergic reaction known as anaphylaxis may rarely occur.

More than one treatment session may be required, particularly for varicose veins on both legs and veins which are very extensive. Bandages and a support stocking are put on the leg after foam sclerotherapy treatment and need to be worn for 10 days. These must be kept dry. Many people develop a few new varicose veins during the years after a foam sclerotherapy. There have not been enough scientific reports on the long term results of foam sclerotherapy to give precise figures.

Laser treatment: You may experience discomfort following laser treatment. You may experience some lumpiness and tenderness in the thigh/back of leg which can take several weeks to settle. You may also get patches of numbness over the vein which will disappear with time. The risk of a deep vein thrombosis following laser treatment is about 1% (1 in 100). Very occasionally, laser treatment can damage the main vein in the leg. Additional treatment in the form of foam sclerotherapy may be required to get rid of all the varicose veins. This may mean returning for treatment on another occasion. Most surgeons advise wearing a support stocking for about 10 days and avoiding getting the legs wet (in a bath or shower) for the 10 days. Many people develop a few new varicose veins during the years after a laser treatment. There have not been enough scientific reports on the long term results of laser treatment to give precise figures.

What are the possible benefits of taking part? We hope that the results from the study may benefit people with varicose veins in the future and will help us recommend the best type of treatment. If you are allocated foam sclerotherapy or laser treatment then you will avoid a general anaesthetic, a groin incision and bruising. But unlike surgery you may need to attend for more than one treatment session. The long term results of surgery are well known but there is much less information available for foam sclerotherapy and laser treatment. After all three treatment options you can become fully active as quickly as you want.

What happens when the research study stops? You will be followed up in the usual way.

What if there is a problem? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed (see part 2 of this leaflet).

Will my taking part be confidential? Yes. All the information about your participation in this study will be kept confidential. The details are included in part 2 of this leaflet.

What if new treatment becomes available? If a new treatment or information becomes available during the study, you will be made aware of this and you may decide whether or not to continue in the study. You may decide this at any time and your decision will not affect the long-term care you receive in the hospital. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information your doctor might consider it to be in your best interest to withdraw from the study. He/she will explain the reasons and arrange for your care to continue. If the study is stopped for any reason you will be told why and your continuing care will be arranged.

What will happen if I don't want to carry on with this study? You can withdraw from the study at any time, but, you should keep attending the hospital to have your varicose veins treated.

What if there is a problem? If you have a concern about any aspect of the study, you should ask to speak with the researchers who will do their best to answer your questions (contact details on page 12 of this leaflet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the hospital.

If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspects of this study, the normal National Health Service mechanisms may be available to you.

Will my taking part in the study be kept confidential? All information that is collected about you during the course of the research will be kept strictly confidential. Personal data from all study participants will be collected and stored at the CLASS Trial Office in Aberdeen. By consenting to take part in this study, you are agreeing that your medical records and data collected during the study may be looked at by individuals directly involved in the trial, from regulatory authorities, from the University of Aberdeen or from the NHS Boards or Trusts, where it is relevant to your taking part in this research. The purpose of this review of your medical records is to ensure that the information about you is correctly recorded in the study documentation. You should be aware that all records of your participation in the study will be handled, stored and destroyed in compliance with the Data Protection Act of 1998.

Will any genetic tests be done? No.

What will happen to the results of the study? When the study is finished all the results will be analysed and the results may be published in a medical journal (while maintaining confidentiality of your identity) and presented at scientific meetings. We will send out a study newsletter every 6 months to keep you updated on the progress of the study.

Who is organising and funding this study? This study is being funded by the NHS National Institute for Health Research Health Technology Assessment programme. The study has been designed by UK vascular surgeons and researchers. Patients will be recruited at different hospitals in England and Scotland. It is being coordinated by the Centre for Healthcare Randomised Trials (CHaRT) located in the Health Services Research Unit at the University of Aberdeen, Scotland.

Will my doctor be paid for including me? The doctor conducting the research will not be paid for including you in the study or looking after you during the course of the study.

Will my own GP know that I am taking part in this study? With your consent, we will inform your GP that you are taking part in the study. We will also ask for your permission to record the name and address of a family member or friend who we could contact if we have

difficulty getting in touch with you during the planned five year follow up period (for example if you moved house). We call this your “best contact”. Please tell them that you have nominated them as your “best contact”.

Who has reviewed the study? This Study has been approved by the Main Research Ethics Committee and Local Research Ethics Committee. The study also is registered and approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

Who can I contact for more information?

[Local recruitment contact details]

Thank you

Patients and doctors rely increasingly on the results of Clinical Trials like the CLASS trial to make sure that they are making the right decisions about treatment. Thank you for taking the trouble to read this information leaflet, we hope that it will have been helpful in enabling you to decide whether or not you would like to help us by participating in this study.

CLASS

**Comparison of LAser, Surgery
and foam Sclerotherapy**

**VARICOSE VEINS AND TREATMENTS
INFORMATION FOR PATIENTS**

BOOKLET 2

We are performing a research study which compares three different treatments for varicose veins: foam sclerotherapy, laser treatment or standard surgery. You will have been provided with the patient study information leaflet on this study (booklet 1). We know that each of the treatments do get rid of varicose veins in the short-term, but they have different advantages and disadvantages. The trial compares how well each treatment works in getting rid of varicose veins and in improving quality of life. It also compares the recovery and the side effects of the different treatments. In addition, the trial will compare the “value for money” of the treatments (that is, how much it costs to give a particular amount of improvement to the quality of people’s lives).

Information in this leaflet is divided into these sections:

1. Information about varicose veins and the problems they can cause.
2. A detailed description of:
 - What happens at the time of each treatment
 - The possible problems and side effects which can occur
 - Advice about the recovery and return to activity after treatment
3. A summary of the possible advantages and disadvantages for each treatment.

For more information, please contact:

[Local recruitment contact details]

Section 1. Information about varicose veins and the problems they can cause.

What are varicose veins?

Varicose veins are veins under the skin of the legs which have become widened, bulging and twisted. They are very common and do not cause medical problems in most people.

Blood flows down the legs through the arteries, and back up the legs through the veins. There are two main systems of veins in the legs - the deep veins which carry most of the blood back up the legs to the heart, and the veins under the skin, which are less important and which can form varicose veins. All these veins contain valves which should only allow the blood to flow upwards. If the veins become widened and varicose these valves no longer work properly. Blood can then flow backwards down the veins and produce a head of pressure when standing, walking about, or sitting. Lying down or "putting your feet up" relieves this head of pressure and usually makes the legs feel better. Both symptoms and treatment depend on how badly the valves in the veins are working, although the inconvenience people get from their varicose veins is very variable.

What problems can varicose veins cause?

Very many people have no symptoms at all from their varicose veins, except for the fact that they are noticeable, and their appearance can be embarrassing. Simply having varicose veins is not a good reason for having treatment. Other than cosmetic embarrassment the common symptoms of varicose veins are aching, discomfort, and heaviness of the legs, which are usually worse at the end of the day. Sometimes the ankle can swell, too. These symptoms are not medically serious, but can be treated if they are sufficiently troublesome. Although varicose veins can get worse over the years, this often happens very slowly and worry that "they might get worse" is not a good reason for treatment if the veins are not causing symptoms.

In a few people the high pressure in the veins causes damage to the skin near the ankle, which can become brown in colour, sometimes with scarred white areas. Eczema (a red skin rash) can develop. If these changes are allowed to progress, or if the skin is injured, an ulcer may result. Skin changes are therefore a good reason for going to see your GP and for referral to a specialist.

Other problems which varicose veins can occasionally produce are phlebitis and bleeding. Phlebitis (sometimes called thrombophlebitis) means inflammation of the veins, and is often accompanied by some thrombosis (clotting of blood) inside the affected veins, which become hard and tender. This is **not** the same as deep vein thrombosis and is not usually dangerous. It does not mean that the varicose veins necessarily have to be treated. The risk of bleeding as a result of knocking varicose veins worries many people, but this is very rare. It will always stop with firm pressure and the veins can then be treated to remove the risk of further bleeding.

How can varicose veins be treated?

The symptoms of varicose veins can often be improved by wearing support stockings or tights. Compression stockings up to the knee (like "flight socks") are often prescribed for people with discomfort, swelling or skin trouble. Many people do not get on well with compression stockings because they find them difficult to put on, or they find them hot and uncomfortable.

People who have troublesome symptoms but for whom compression hosiery is not an acceptable long-term solution can have treatment to get rid of their varicose veins.

This trial is comparing three treatments which remove the varicose veins or seal them off so that they shrivel up. These three treatments are described in this leaflet.

Section 2. A detailed description of each treatment, possible problems and side-effects, and advice about recovery and return to activity.

Foam Sclerotherapy - the procedure

How long will I be in hospital for foam treatment? Foam sclerotherapy is done as an outpatient. The arrangements differ from hospital to hospital: sometimes the procedure is done in an outpatient clinic and sometimes in an operating theatre.

What happens before the treatment? When you arrive at the clinic a nurse will meet you and will measure your legs for stockings. The surgeon doing the foam treatment will talk with you about what is going to happen. You need to remove your trousers and socks or stockings for the treatment. It is best not to wear tight trousers as you may have difficulty putting them on over the bandage and stocking afterwards.

What happens during foam sclerotherapy treatment? Foam sclerotherapy involves one or more injections into veins of the leg, which are given while you are lying on a couch. These injections are often carried out with the help of ultrasound pictures to be sure that the tip of the needle is correctly positioned in the vein. If the vein is easy to see and feel then ultrasound may not be required. Depending on the vein being injected and the type of needle used, an injection of local anaesthetic may be given first. Sometimes gaining safe and secure access to a vein may need more than one attempt: it is very important to be sure that foam is not injected outside the vein.

After the needles have been secured in selected veins, the leg is usually elevated before foam is injected. Pressure may be applied to the groin or elsewhere to prevent foam entering deeper veins. Nevertheless, after each injection you will be asked to move the foot up and down at the ankle in order to pump blood through the deeper veins, just in case any foam has entered them – movement of the calf muscles flushes away any small amounts of foam.

Following injection, pads and bandages are applied to the leg, and then a firm stocking. These need to be worn for 10 days. During that time you cannot get the bandaged part of the leg wet in a bath or shower.

Foam sclerotherapy treatment takes about half an hour in total. Keep one hour free in case of delays.

After treatment – leaving hospital. You can get up and walk normally immediately after foam sclerotherapy. It is a good idea to go for a walk for about five minutes after getting dressed, to encourage blood flow through the veins. You can leave the hospital shortly after the treatment. We will arrange a follow-up appointment at about 6 weeks after the procedure.

Foam Sclerotherapy - Recovery

How much does it hurt afterwards? Other than the inconvenience of the bandages and stocking, foam sclerotherapy does not usually cause any immediate discomfort after treatment. The varicose veins become hard, lumpy and tender: this can last for several days, and sometimes persists for weeks, but gradually settles. If the veins are particularly uncomfortable or inflamed, you can take an anti-inflammatory painkiller like ibuprofen (Nurofen). Paracetamol is an alternative, particularly if you have had any gastric acid problems or asthma which prevent you from taking medicines like ibuprofen.

What about the bandages and support stockings? Your bandages and stocking must remain in place for 10 days. After this time you can remove them. Throw away the bandages and padding, but keep the stocking (do wash it) in case you need further treatment.

Showering and bathing. Because of the bandages and stocking, you cannot have a normal bath or shower for 10 days after foam sclerotherapy. A shower may be possible by securing a large plastic bag over the leg or by using a special waterproof cover such as a Limbo waterproof protector (Thesis Technology, Chichester OP18 8AT or on prescription). After the bandages have been removed you can shower or bath normally.

Activity. Aim to get back to all your normal activities just as soon as you are able. The **only** special restriction is bathing and showering, which you cannot do normally for 10 days (see above). The only limitation to your activity might be discomfort and tenderness (which can be minimised by taking painkillers) and the need to wear the bandaging and stocking.

Walking. You should start to walk about as soon after foam sclerotherapy as you are able. You can walk as much as you want, as soon as you want. Your thigh may be uncomfortable and tender to the touch in places. You will not cause any damage by walking. Take painkillers if you need them.

There is *no* special advantage in going for a single long walk during the day, although you may walk as far as you wish. Frequent walking is more important than walking a long distance.

Standing and sitting. During the first week after foam sclerotherapy, try to avoid prolonged standing, or sitting with the foot on the floor continuously for longer than about half an hour at a time. Every half hour or so, go for a short walk about or do a few “tip-toe” exercises. If you are sitting or resting for any length of time try to put your foot up - either on a stool or couch or on your bed.

When can I return to work and play sports?

Work. This varies a lot between different people. Most people are able to return to work within two or three days after the treatment. Some people go back to work the following day or even the same day.

Sports. You can return to work and sporting activity as soon after foam sclerotherapy as you feel sufficiently comfortable. Avoid contact sports while you are still in support stockings or bandages, and thereafter start with some gradual training, rather than in immediate competition. Do not go swimming until your bandage has been removed.

Driving. You can drive as soon as you feel confident that you can make an emergency stop safely: practise this before you drive. We would advise you not to drive yourself home following foam sclerotherapy but other than that you can drive as soon as you feel able.

Air travel. The risk of deep vein thrombosis during long air flights or other long journeys in cramped seating is very low, but it is probably best to avoid this kind of travel for about a month after foam sclerotherapy.

Foam Sclerotherapy - risks

What problems can occur after foam sclerotherapy?

Inflammation. The injected veins may be somewhat inflamed and hard for a few days (like phlebitis). This is because the foam sclerotherapy works by causing some inflammation of

the vein walls, which helps them glue together. Occasionally inflammation can be more severe and painful. If this occurs then an anti-inflammatory painkiller such as ibuprofen (Nurofen) will help to settle the symptoms.

Lumpiness and hardness. The injected veins sometimes remain lumpy and hard for many weeks after treatment, but they gradually shrivel.

Damage to skin. Rarely, the skin at the injection site may break down and require treatment.

Bruising and discolouration. A little bruising may occur after foam sclerotherapy. In some people, brownish discolouration of the skin occurs in the areas where the veins were. Usually this fades, but occasionally discolouration may persist: this is more noticeable in people with naturally pale skin.

Thread veins. Any kind of sclerotherapy can occasionally be followed by the appearance of tiny red or blue veins in the area which was injected. This is uncommon.

Headache/migraine-like symptoms. Occasionally, people report headache, or migraine-like symptoms after foam sclerotherapy. It is thought that these are more common in people who have experienced frequent or severe migraines in the past. For this reason, in this study, we do not treat people with foam sclerotherapy if they have had frequent or severe migraines in the past.

Deep vein thrombosis (DVT). Deep vein thrombosis causes swelling of the leg and can result in a blood clot passing to the lungs. It is a possible complication after varicose vein surgery, but the risk is considerably reduced if you start moving your legs and walking frequently soon after the operation. Sometimes, injections are given so that blood clots less than normal: this reduces the risk of thrombosis but increases bruising. The risk of DVT is about 1% (1 in 100 patients). Rarely, a clot like this may break up and travel to the lungs.

Injection into the artery. Many thousands of patients have been treated with foam sclerotherapy. Among these, there have been three reported cases of foam being injected into an artery rather than a varicose vein.

Concern about stroke and loss of vision. This has been a cause for concern, but there is no good evidence that it is a real risk when normal amounts of foam are used. The reasons for the concerns have been:

- There is a possibility that small amounts of foam could circulate in the blood stream, and, in particular, they could pass through small 'holes in the heart' which are present in some otherwise fit people. Theoretically this could allow foam to pass to small blood vessels – for example those in the eye or brain.
- Some patients have reported temporary disturbance of vision (i.e. blurred vision or loss of vision) after foam sclerotherapy. The risk of this happening is about 1% (1 in 100). There has been concern that any disturbance of vision might be due to tiny bubbles entering small blood vessels in the back of the eye. The very few patients in whom this has been reported have all rapidly recovered their full vision, generally within 30 minutes. The worry that air bubbles might cause permanent loss of vision is a theoretical one: it has not been reported as having happened.
- Stroke and mini-stroke (transient ischemic attack) have been described in a very few patients worldwide. One case of stroke was in a patient in whom a large volume of foam was used (much larger than is now recommended). All the surgeons involved in this study limit the amount of foam that is used at any one time and this minimises the risk of stroke.

Temporary confusion: Among the thousands of patients that have been treated throughout the world with foam, a few patients have experienced some temporary confusion after the treatment. Any confusion is likely to be very short-term (lasting only a few minutes).

Concern about fit. One patient has had a fit following foam, but it is unclear if this was related to the foam treatment.

Anaphylaxis/Allergic reaction. This is rare and may cause a rash and a fall in your blood pressure. In extreme cases you may lose consciousness. In the unlikely event that this may occur, equipment and the necessary drugs will be available to enable the doctor and nurse to treat you immediately.

Varicose veins coming back.

Many people develop a few new varicose veins during the years after foam sclerotherapy. There have not been enough scientific reports on the long term results of foam sclerotherapy to give precise figures. Varicose veins may simply re-grow in the areas which have been dealt with, or they may develop in different veins which were normal at the time of the original treatment. If veins develop again they can be treated.

Laser only or laser plus foam sclerotherapy - Procedure

Laser treatment is used to seal off the main vein under the skin in the thigh or the calf. This takes away the head of pressure which causes varicose veins to bulge and cause symptoms. Sometimes we need to use a combination of laser treatment in the thigh and foam sclerotherapy of the main vein at the knee or upper calf. If required, this will be done at the same treatment session.

Laser treatment alone may cause the varicose veins to disappear or reduce in size, but if visible varicose veins remain after the laser treatment, you may wish to have them treated by foam sclerotherapy. Foam sclerotherapy may be done at one or more later treatment sessions. One hospital in the study uses phlebectomies (removal of veins through tiny incisions) at the same time as laser treatment.

How long will I be in hospital for laser treatment? You will have your treatment performed as an outpatient. The procedure itself takes about 45 minutes. You will be in the hospital for about 2 hours in total, but you should keep half a day free in case of delays.

What happens before the treatment? When you arrive a nurse will meet you and will measure your legs for stockings and show you where to get changed. It is best not to wear tight trousers as you may have difficulty putting them on over the stocking afterwards.

The consultant or a member of the surgical team will talk with you about what is going to happen and will mark your varicose veins with a felt tip pen.

What happens during laser treatment? An injection of local anaesthetic is given to freeze the skin just above, or just below, the knee or in the calf. Once the skin is numb a needle is inserted into a vein beside the knee. A wire is then passed up the vein to the groin and the laser filament is passed over the wire. You will not feel this. The position of the laser filament is checked using an ultrasound scanner. The area around the vein and the skin is then made numb using cold local anaesthetic injections from the knee to the groin. This usually requires 4 or 5 injections with a small needle.

The laser is fired as it is gradually pulled back down the vein from the groin to the knee. This should not be painful because of the local anaesthetic, but you may feel some pushing, pulling or mild discomfort during the procedure. If you feel anything more than this you should say so: the procedure can then be temporarily stopped to settle this.

The heat from the laser closes (cauterises) the vein from the inside. Lasers are powerful sources of energy and you and all the staff will wear protective goggles during the time that the laser is working.

When the vein has been sealed up, the laser is removed from the leg and a firm stocking is applied. This needs to be worn for 10 days. During that time you cannot get the stocking wet in a bath or shower.

After treatment – leaving hospital. Immediately following the procedure, once you have got dressed, you should go for a 10 minute walk. Once you have been for a walk we will offer you a cup of tea and you are then free to go home.

We will arrange a check up for you about 6 weeks after the procedure. By that time most of the varicose veins in your leg should have shrunk and many, or all of them may have disappeared. If there are any left they can be treated by foam sclerotherapy.

Laser - Recovery

How much does it hurt afterwards? You may experience some discomfort or pulling on the inside of your thigh following the treatment. This may be most noticeable for about one week after treatment, but it then settles down.

People vary a lot in the amount of pain they experience after laser treatment, though most experience discomfort only. You will be encouraged to get up and walk immediately following the laser treatment.

You will be given a supply of an anti-inflammatory drug, such as ibuprofen (Nurofen) or diclofenac (Voltarol) which are also painkillers. We recommend that you take these regularly for three days. If you have had a stomach ulcer, or asthma then you should not take anti-inflammatory drugs of this kind: tell us and we will supply you with a painkiller which suits you.

If any discomfort occurs after three days, take a simple painkiller such as paracetamol (Panadol).

What about my wound? The small cut beside your knee where the laser fibre was inserted is closed with an adhesive strip. It can be removed when your stocking is removed.

What about the bandages and support stockings? Your stocking must remain in place for 10 days after which time you can remove it. Do not get the stocking wet during these 10 days. Please keep the stocking (do wash it) in case you need further treatment.

Bathing and showering. Because of the stocking, you cannot have a normal bath or shower until 10 days after laser treatment. A shower may be possible by securing a large plastic bag over the leg or by using a special waterproof cover such as a Limbo waterproof protector (Thesis Technology, Chichester OP18 8AT or on prescription).

What should I expect my leg to be like after laser treatment? You may be aware of areas of lumpiness on the leg which may be slightly tender. This is caused by some inflammation in the vein that has been treated. It is not harmful and will gradually go away, but this may take several weeks. The inner side of your thigh may be uncomfortable during the first few days.

Activity. Aim to get back to all your normal activities just as soon as you are able. The **only** special restriction is bathing and showering, which you cannot do normally for 10 days (see above). The only limitation to your activity might be discomfort and tenderness (which can be minimised by taking painkillers) and the need to wear the stocking.

Walking. You should start to walk about as soon after laser treatment as you are able. You can walk as much as you want, as soon as you want. Your thigh may be uncomfortable and tender to the touch in places. You will not cause any damage by walking. Take painkillers if you need them.

There is *no* special advantage in going for a single long walk during the day, although you may walk as far as you wish. Frequent walking is more important than walking a long distance.

Standing and sitting. During the first week after laser treatment, try to avoid prolonged standing, or sitting with the foot on the floor continuously for longer than about half an hour at a time: go for a short walk about or do a few “tip-toe” exercises. If you are sitting or resting for any length of time try to put your foot up - either on a stool or couch or on your bed.

When can I return to work and play sports?

Work. This varies a lot between different people. Most people are able to return to work within two or three days after the treatment – some people go back the following day or even the same day.

Sports. You can return to work and sporting activity as soon after treatment as you feel sufficiently well and comfortable. Avoid contact sports while you are still in support stockings or bandages, and thereafter start with some gradual training, rather than in immediate competition. Do not go swimming until your bandage has been removed. We suggest avoiding strenuous activity like the gym for about 2 weeks after the procedure.

Driving. You can drive as soon as you feel confident that you can make an emergency stop safely: practise this before you drive. We would advise you not to drive yourself home following the laser treatment, but other than that you can drive as soon as you feel able.

Air travel. The risk of deep vein thrombosis during long air flights or other long journeys in cramped seating is very low, but it is probably best to avoid this kind of travel for about a month after your treatment.

Laser - risks

What problems can occur after the laser treatment?

Bruising. Some bruising is normal, and occasionally the leg becomes very bruised. This bruising appears during the first few days after laser treatment: it will all go away over a period of weeks.

Aches, twinges, and areas of tenderness may all be felt in the legs for the first few days after the laser treatment. These will settle down, and should not discourage you from becoming fully active as soon as you are able.

Tender lumps under the skin are common and are caused by blood clots that have collected in the places where the vein has been treated. They are not dangerous and will gradually disappear. It may take up to 12 weeks for all the lumps to disappear. Occasionally they can be quite painful during the first two weeks or so.

Numbness. Areas of numbness in the skin can occasionally occur at the places where varicose veins were treated. This is because tiny nerves may be damaged by heat from the laser. This will not affect the movement of your foot or your walking. The numbness will usually recover over a period of several weeks.

Thread veins. Laser treatment can occasionally be followed by the appearance of tiny red or blue veins in the area which was injected. This is uncommon.

Deep vein thrombosis (DVT). Deep vein thrombosis causes swelling of the leg and can result in a blood clot passing to the lungs. It is a possible complication after varicose vein surgery, but the risk is considerably reduced if you start moving your legs and walking frequently soon after the operation. Sometimes, injections are given so that blood clots less than normal: this reduces the risk of thrombosis but increases bruising. The risk of DVT is about 1% (1 in 100 patients). Rarely, a clot like this may break up and travel to the lungs.

Damage to major vein. Damage to the major veins in the leg is a rare complication of laser treatment, which we take great pains to avoid.

The risks of additional foam sclerotherapy. Remember that you may require foam sclerotherapy, in addition to laser treatment, to get rid of all your varicose veins.

Will varicose veins come back? Many people develop a few new varicose veins during the years after laser treatment. There have not been enough scientific reports on the long term results of laser treatment to give precise figures. Varicose veins may simply re-grow in the areas which have been dealt with, or they may develop in different veins which were normal at the time of the original treatment. If veins develop again they can be treated.

Surgery - procedure

How long will I be in hospital for surgery? If you are medically fit and have somebody at home with you then a day case operation is usual. If you have medical conditions, if you live some distance away or if you are having surgery for extensive varicose veins in both legs, then you may have your operation as an in-patient (you may be admitted the day before your operation for the doctors and nurses to assess your needs; or on the morning of the operation, and then stay overnight).

What happens before the treatment? A member of the surgical team will check that all the necessary preparations have been made and will mark your varicose veins with a felt pen. Be sure that all the veins you would like dealt with have been marked, and ask about any which have not.

Shaving may be done before your operation or in the operating theatre. If you are going to have an incision in the groin, this area will need to be shaved, but there will be no need to shave all the pubic hair. The leg will need to be shaved, at least in the areas of the varicose veins which are going to be removed. This makes marking of your varicose veins easier and means that hairs do not get into the wounds during the operation.

What happens during surgery? Surgery is usually done under a general anaesthetic. An incision (2 – 4 cm long) is made over the top of the main vein in the crease of the groin or behind the knee. It is tied off just where it joins the deep vein, so relieving the “head of pressure” on the varicose veins further down the leg. This incision is closed with stitches, which are hidden under the skin.

The vein is removed by passing a fine wire down it and making a small incision (less than 1 cm long) near the knee – “stripping”. This helps to guard against varicose veins forming

again. Blood flows up the many other veins in the leg after this vein has been removed and it is therefore safe to remove this vein.

Varicose veins marked before the operation are removed through tiny cuts (“phlebectomies”). These cuts can be closed with stitches or adhesive strips.

After treatment – leaving hospital. You can get up and walk about as soon as the effects of the anaesthetic have worn off, shortly after the operation. If you are being treated as a day case, after two or three hours you should feel fit enough to go home. Before you leave the hospital staff will check your leg. They will give you a note for your GP, and some painkillers to take with you. They will make arrangements for you to visit a practice nurse the next day (or if necessary for a nurse to call) to check on you and change your bandages for a support stocking.

If you are treated as an inpatient, the bandages on your leg/s will be changed on the morning after your operation for a support stocking. You will normally be able to go home shortly afterwards.

Surgery - recovery

How much does it hurt afterwards? We inject a long acting local anaesthetic into the groin wound at the end of the operation. This is usually the most uncomfortable area. People vary a lot in the amount of pain they experience after the operation, though most experience mild discomfort only. It is more uncomfortable to get up and walk after operation to both legs than when only one leg has been dealt with. In either case you will be encouraged to get up and walk on the day of your operation when the effects of the anaesthetic have worn off sufficiently.

Painkillers such as paracetamol or anti-inflammatory painkillers like ibuprofen (Nurofen) or diclofenac (Voltarol) will be prescribed for you to take after the operation. It is important that you should take these if you need them to walk about and to rest with comfort. You should not need them for more than a few days, but the duration of discomfort varies from person to person. Occasionally tender lumps of old blood clot (haematoma) beneath the skin can become inflamed and very tender. This is not infection, but you may require to take anti-inflammatory drugs for a longer period.

Will I have dressings or stitches? Stitches are placed under the skin in the groin and do not have to be removed. If the surgeon has used a dressing on the groin, this can be removed after 48 hours. The groin wound can be washed and gently dried from 48 hours after the operation, to keep the area fresh and clean.

The small incisions further down the leg are closed with adhesive strips and it is best to keep these dry for 10 days. 10 days after the operation you can remove the strips yourself: this is often easiest in the bath or shower which helps to loosen them. After that time there is no restriction at all in taking a shower or bath.

What should I expect my leg to be like after surgery? Bruising is common after varicose vein operations. It is sometimes quite extensive and may take a month or more to settle. In particular it can occur on the inner side of the thigh, where may be no incisions. This is caused by removing the main vein under the skin from this area. Hard lumps are also common – they represent bruising in places where the varicose veins used to be. Any bruising and lumpiness may be tender but you will do no harm by becoming active. Take painkillers if you need them.

What about bandages and support stockings? Your bandages will be changed for support stocking/s the day after operation. Wear these for 10 days after the operation. There is no need to wear the stockings after removing the adhesive strips 10 days after the operation (but if you feel more comfortable with them for another few days this is quite

alright). If you find the stocking/s uncomfortable or excessively hot, it is reasonable to remove them four or five days after the operation, provided you are easily and frequently active. An alternative is to remove them at night only, and to put them on each day – but some people find it difficult putting them back on. They are mainly intended to support the leg while you are up and about during the day.

Bathing and showering.

Groin wounds: You can wash your groin wound gently after 48 hours, as described above.

Keep all the other wounds dry for 10 days so that they properly heal. At 10 days you can soak the adhesive strips off in a bath or shower.

You cannot have a normal bath or shower until 10 days after the operation. Before 10 days, some people manage a shallow bath by putting their leg up on the side of the bath to keep it dry, if there are no wounds or dressings above the knee. A shower may be possible before 10 days by securing a large plastic bag over the leg or by using a special waterproof cover such as a Limbo waterproof protector (Thesis Technology, Chichester OP18 8AT or on prescription). If any of the adhesive strips do come off early, the little wound beneath it is likely to be quite alright but you can cover it with a plaster (e.g. Bandaid) if you want.

Activity. Aim to get back to all your normal activities just as soon as you are able. The ***only*** special restriction is bathing and showering, which you cannot do normally for 10 days (see above).

The only limitation to your activity should be discomfort and tenderness from bruising which can be minimised by taking painkillers. If you can get back to all the things you would like to do within a few days of the operation, then do so. The time taken to get fully back to all activities varies quite a lot between different people. If you had many large veins then you are more likely to be bruised and tender. Do not let this put you off becoming active: you will do no harm.

Walking. You should start to walk about as soon after the operation as you are able. You can walk as much as you want, as soon as you want. Getting up from a seated position or bed is sometimes a little uncomfortable during the first two or three days after the operation, particularly where the groin or the area behind the knee has been operated on. The whole leg may be stiff, and tender to the touch in places. You will not damage any of the wounds by walking. Take painkillers if you need them.

There is *no* special advantage in going for a single long walk during the day, although you may walk as far as you wish. Frequent walking is more important than walking a long distance.

Standing and sitting. During the first week after surgery, try to avoid prolonged standing, or sitting with the foot on the floor continuously for longer than about half an hour at a time: go for a short walk about or do a few “tip-toe” exercises. If you are sitting or resting for any length of time try to put your foot up - either on a stool or couch or on your bed.

When can I return to work and play sports?

Work. You can return to work as soon after the operation as you feel sufficiently well and comfortable. After an operation on one leg there is no reason to anticipate being away from “office” or sedentary work for more than two or three days. If your job involves prolonged standing (without the opportunity to walk about) or driving, then you should wear the support stocking if you return to work within two weeks of the operation. We hope that people will be back at work within a week after surgery to one leg and two weeks after surgery to both legs – but there is no reason to remain off work that long if you can manage with reasonable comfort.

Sports. Be guided by how your legs feel: bruising and tenderness may limit you from being very active or from some activities in the first few days after the operation, but you can do whatever is comfortable. Avoid very strenuous leg exercise (e.g. running) during the first week, and thereafter it is usually best to start with some gradual training, rather than in immediate competition. Do not go swimming until all the wounds are healed and dry (at least 10 days).

Driving. You should not drive within 24 hours of a general anaesthetic. Thereafter you can drive as soon as you feel confident that you can make an emergency stop without pain: practise this before you drive.

Air travel. The risk of deep vein thrombosis during long air flights or other long journeys in cramped seating is very low, but it is probably best to avoid this kind of travel for about a month after your operation.

Surgery - risks

What problems can occur after surgery?

Discomfort. Aches, twinges, and areas of tenderness may be felt in the legs for the first few weeks. These will settle down, and should not discourage you from becoming fully active as soon as you are able.

Lumps. Tender lumps under the skin are common (especially in the thigh) and are caused by blood clots which have collected in the places where the veins were removed. They are not dangerous and will gradually disappear but this can take several weeks. Occasionally they can be quite painful during the first two weeks or more. It is common for the area under the groin wound to feel tender for a few days and thickened for a few weeks.

Infection. Infection is an occasional problem, particularly in groin wounds. It is more of a risk in people who are overweight and after operation for recurrent varicose veins. Infection usually settles with antibiotic treatment. If the wound was closed by a stitch under the skin, this may need to be removed to allow the infection to clear up. If an abscess forms, this may need to be drained at an operation under general anaesthetic and the wound will then require dressings – sometimes for up to a month.

Scars and blemishes. The scars on your legs are easily noticeable to start with, but will continue to fade for many months after the operation. Very occasionally, some people develop a little brown staining where the veins were removed. Another uncommon but disappointing problem is the appearance of tiny thread veins or “blushes” on the skin in the areas where varicose veins were removed.

Nerve damage. Nerves under the skin can be damaged when removing varicose veins close to them and small areas of numbness are quite common. If a nerve lying alongside one of the main veins under the skin is damaged, then a larger area of numbness can be caused. If this happens after surgery to the main vein on the inner side of the leg, then numbness will result over the inner part of the lower leg and foot. If a main vein behind the knee needs to be dealt with, then there is a risk to the nerve which conducts feeling from the skin on the outer part of the lower leg and foot. Areas of numbness often get better over weeks or months, but sometimes they persist in the long term.

Damage to major structures. Damage to major arteries, veins, and the main nerve which allows the leg to move normally have all happened during varicose vein operations, but are very rare complications (less than 1 in 10,000), which we take great pains to avoid.

Swelling. Damage to the tiny lymphatic vessels which drain tissue fluid from the foot and leg, and which run close to the veins, can occasionally cause problems. Swelling of the foot and ankle can occur, which usually settles over a period of several weeks, but very rarely it

may persist. Tissue fluid may rarely collect under the groin wound, forming a swelling (which usually goes away after a time) or very occasionally tissue fluid may leak from the groin wound. These problems are all more common after operations for recurrent varicose veins.

Deep vein thrombosis (DVT). Deep vein thrombosis causes swelling of the leg and can result in a blood clot passing to the lungs. It is a possible complication after varicose vein surgery, but the risk is considerably reduced if you start moving your legs and walking frequently soon after the operation. Sometimes, injections are given so that blood clots less than normal: this reduces the risk of thrombosis but increases bruising. The risk of DVT is about 1% (1 in 100 patients). Rarely, a clot like this may break up and travel to the lungs.

The risks of a general anaesthetic. Varicose vein operations are almost always done under a general anaesthetic. General anaesthetics have some risks, which may be increased if you have chronic medical conditions, but in general they are as follows:

Common temporary side-effects (risk of 1 in 10 to 1 in 100) include bruising or pain in the area of injections, blurred vision and sickness (these can usually be treated and pass off quickly).

Infrequent complications (risk of 1 in 100 to 1 in 10,000) include temporary breathing difficulties, muscle pains, headaches, damage to teeth, lip or tongue, sore throat and difficulty speaking.

Extremely rare and serious complications (risk of less than 1 in 10,000). These include severe allergic reactions and death, brain damage, kidney and liver failure, lung damage, permanent nerve or blood vessel damage, eye injury, and damage to the voice-box. These are very rare and may depend on whether you have other serious medical conditions.

Varicose veins coming back. Many people develop a few new varicose veins during the years after a varicose vein operation and five years after operation about one person in eight has troublesome varicose veins again. Varicose veins may simply re-grow in the areas which have been dealt with, or they may develop in different veins which were normal at the time of the original operation. If veins develop again they can be dealt with by injections or a further operation should they be troublesome.

Section 3. Summary of the possible advantages and disadvantages for each treatment

Possible advantages and disadvantages of foam sclerotherapy.

- Foam sclerotherapy is done under local anaesthetic, but sometimes no anaesthetic is required at all.
- No surgical incisions are required.
- The veins which have been treated may remain lumpy, hard and sometimes tender for several weeks or even months.
- More than one treatment session may be required, particularly for varicose veins on both legs and for veins which are very extensive.
- You can become fully active as quickly as you want after foam sclerotherapy treatment.
- Bandages and a support stocking are put on the leg after foam sclerotherapy treatment, and need to be worn for about 10 days. These must be kept dry.
- Varicose veins may gradually reappear in the years after foam sclerotherapy treatment: this is rather more likely than after surgery. They can be treated with further foam sclerotherapy if required.
- In summary, foam sclerotherapy is a simple treatment to have but firm compression from support stockings is important afterwards. The treated veins may be hard and tender for some time and there may be some brown staining. Repeat treatment sessions may be needed, particularly if there are varicose veins in both legs. New veins may gradually appear.

Possible advantages and disadvantages of laser treatment.

- Laser treatment can be done under local anaesthetic, rather than general anaesthetic.
- No incision is needed in the groin
- It avoids the bruising which can sometimes occur after standard surgery, but you may experience some lumpiness and tenderness in the thigh which can take several weeks to settle.
- Foam sclerotherapy or phlebectomies may be required to get rid of all the varicose veins. This may mean returning for treatment on another occasion.
- You can become fully active as quickly as you want after laser treatment.
- Most surgeons advise wearing a support stocking for 10 days and avoiding getting the legs wet (in a bath or shower).
- Laser treatment seems to give results as good as surgery up to five years but varicose veins may gradually reappear over the years.
- In summary, laser treatment can be done under local anaesthetic, requiring several injections into the thigh. Additional treatment may be needed to get rid of all the varicose veins.

Possible advantages and disadvantages of standard surgery.

- Standard surgery removes all the varicose veins at a single procedure. It should not be necessary to have anything more done to get rid of any remaining varicose veins.
- Varicose vein surgery is normally done under a general anaesthetic.
- Bruising is common. People with smaller varicose veins may get very little bruising but people with big varicose veins may be very bruised. All the bruising goes away.
- There may be some discomfort from the groin wound and occasionally the groin wound can become infected.
- You can become fully active as quickly as you want after standard surgery.
- Most surgeons advise wearing a support stocking for the first 10 days and avoiding getting the legs wet (in a bath or shower) during this time.
- Standard surgery gives a good long term result to many people but varicose veins may gradually reappear over the years.
- It is a tried and tested treatment which has been used for many years.
- In summary, surgical treatment involves a general anaesthetic, an incision in the groin and often some bruising. However, all the varicose veins can be dealt with thoroughly by a single treatment, in one or both legs.



Comparison of LAser, Surgery and foam Sclerotherapy

Inclusion criteria

- Adult patients (aged over 18 years old) referred for treatment of primary varicose veins
- Symptomatic (CEAP grade 2 or above) primary long or short saphenous main stem incompetence (reflux >1 second on duplex scanning)
- Suitable for laser, foam sclerotherapy or surgery

Clinic date
.....

Study Number	Patient Name	Does the patient fulfill the inclusion/exclusion criteria?	Is the patient potentially interested in taking part?	<i>If not eligible or declines to participate, state reason (A, B, C, D or E)</i>	If eligible and interested, record contact telephone number	Rx rec'd (F/S/L)
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>			

Exclusion criteria

<p>A0: No varicose veins A1: Thread veins A2: Non-symptomatic (CEAP 1/2) A3: No truncal reflux, or truncal reflux <1second A4: Long or short saphenous less than 3mm or greater than 15mm in diameter A5: Recurrence A6: Tortuous veins that are considered unsuitable for EVLA A7: Thrombosis (Current deep vein or acute superficial vein thrombosis)</p>	<p>B: Patient co-morbidity</p> <ul style="list-style-type: none"> • Cardiac failure • Pulmonary oedema • Local or systemic infection • Pregnancy or breast feeding • History of hypercoagulability • Inability to mobilise post-procedure • Varicosities caused by pelvic or abdominal tumours • Arterial disease (ankle brachial pressure index <0.8) • Patients who are not fit for a general anaesthetic due to significant systemic disease, morbid obesity or other causes. • Migraines which are frequent, or migraines which are severe enough to require hospitalisation 	<p>C: Other</p> <ul style="list-style-type: none"> • Allergy to sclerosant • Needle phobia • Inability to complete questionnaires <p>D: Non attendance (DNA/CNA) E1: Refusal - preference surgery E2: Refusal - preference foam E3: Refusal - preference laser E4: Refusal - reason other than preference</p>
---	--	--



Comparison of LAser, Surgery and foam Sclerotherapy

Study Number

--	--	--	--	--	--

TRIAL CONSENT FORM

Please initial ALL boxes

By signing this form and initialling each box I agree that I have:

- read and understood the patient information leaflet (Version number, dated) for the above study and kept a copy
- discussed this study with Dr/Mr/Mrs/Ms and all my questions have received satisfactory answers
- understood the purpose of the study and I know what my involvement will be

I understand that:

- my participation is voluntary
- if further funding is obtained I will be followed up for five years
- I am free to withdraw from the study at any time without having to give a reason
- if I withdraw, this will not affect my care
- my personal data will be collected and stored at the Trial office in Aberdeen
- information relevant to the CLASS trial may be collected from my hospital and NHS records, including Office of National Statistics (ONS) and NHS central registers
- relevant sections of my medical notes and data collected during the study may be looked at by individuals directly involved in the trial, from regulatory authorities, from the University of Aberdeen or from the NHS Boards or Trusts, where it is relevant to my taking part in this research.

I agree that my family doctor (GP), my hospital consultant and the person I have nominated as my best contact may be told that I am taking part in this study

I agree to take part in the study

Your signature (participant) _____

Your name in block capitals _____

Date _____

For office use only I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved.

Signature _____

Date _____

CLASS Trial Office, Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD
Phone 01224 XXXXXX; Fax 01224 XXXXXX; xxxxxxxx@abdn.ac.uk

Copies: 1 for patient; 1 for study notes, 1 for researcher in Aberdeen; 1 to be filed with hospital notes.



CONTACT DETAILS

Comparison of LAser, Surgery
and foam Sclerotherapy

Study number

--	--	--	--	--	--

PATIENT DETAILS

Title Mr Mrs Miss Ms Other

First name

Surname

Date of birth / /

Address

Home telephone

Mobile telephone

Work telephone

GP DETAILS

Initials Surname

Address

BEST CONTACT DETAILS

Title Mr Mrs Miss Ms Other

First name

Surname

Address

Telephone number

RELATIONSHIP OF BEST CONTACT TO PATIENT

Relative

Friend



Comparison of LAser, Surgery
and foam Sclerotherapy

BASELINE CLINICAL DATA

Study Number

--	--	--	--	--	--

AFFECTED LEG(S)

Right leg only

Left leg only

Both legs

STUDY LEG (in case of bilaterality, study leg designated as worst leg by patient)

Right leg

Left leg

LEFT LEG: CEAP CLASSIFICATION

Please tick appropriate response

- C0 No visible or palpable signs of venous disease.
- C1 Telangiectasis or reticular veins. Veins less than 3 mm
- C2 Varicose veins. Veins over 3 mm
- C3 Edema
- C4 Skin and subcutaneous changes
- C4a Pigmentation or eczema
- C4b Lipodermatosclerosis or atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer

LEFT LEG: Venous Clinical Severity Score (VCSS)

Left leg affected by varicose veins

Yes

No

If yes, complete VCSS by ticking **one box in each row**

PAIN

None

Occasional, not restricting activity or requiring analgesics

Daily, moderate activity limitation, occasional analgesics

Daily, severe limiting activities or requiring regular use of analgesics

VARICOSE VEINS i.e. >3mm

None

Few, scattered branch varicose veins

Multiple: LSV varicose veins confined to calf or thigh

Extensive: thigh and calf or LSV and SSV distribution

VENOUS EDEMA

None

Evening ankle only

Afternoon edema, above ankle

Morning edema above ankle and requiring activity change, elevation

SKIN PIGMENTATION

None or focal, low intensity (tan)

Diffuse, but limited in area and old (brown)

Diffuse over most of gaiter area (lower 1/3) or recent pigmentation (purple)

Wider distribution (above lower 1/3), recent pigmentation

INFLAMMATION

None

Mild cellulitis, limited to marginal area around ulcer

Moderate cellulitis, involves most of gaiter area (lower 2/3)

Severe cellulitis (lower 1/3 and above) or significant venous eczema

INDURATION

None

Focal, circum-malleolar (<5 cm)

Medial or lateral, less than lower 1/3 of leg

Entire lower 1/3 of leg or more

ACTIVE ULCERS, N

0

1

2

>2

ACTIVE ULCERATION DURATION (longest duration; if 3 months, select >3 months)

None

<3 months

>3 months, <1year

Not healed >1 year

ACTIVE ULCER, SIZE (largest ulcer)

None

<2 cm diameter

2-6 cm diameter

>6 cm diameter

COMPRESSIVE THERAPY

Not used or not compliant

Intermittent use of stockings

Wears elastic stockings most days

Full compliance: stockings + elevation

RIGHT LEG: CEAP Classification

Please tick appropriate response

- C0 No visible or palpable signs of venous disease.
- C1 Telangiectasis or reticular veins. Veins less than 3 mm
- C2 Varicose veins. Veins over 3 mm
- C3 Edema
- C4 Skin and subcutaneous changes
- C4a Pigmentation or eczema
- C4b Lipodermatosclerosis or atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer

RIGHT LEG: Venous Clinical Severity Score (VCSS)

Right leg affected by varicose veins

Yes

No

If yes, complete VCSS by ticking **one box in each row**

PAIN

None

Occasional, not restricting activity or requiring analgesics

Daily, moderate activity limitation, occasional analgesics

Daily, severe limiting activities or requiring regular use of analgesics

VARICOSE VEINS i.e. >3mm

None

Few, scattered branch varicose veins

Multiple: LSV varicose veins confined to calf or thigh

Extensive: thigh and calf or LSV and SSV distribution

VENOUS EDEMA

None

Evening ankle only

Afternoon edema, above ankle

Morning edema above ankle and requiring activity change, elevation

SKIN PIGMENTATION

None or focal, low intensity (tan)

Diffuse, but limited in area and old (brown)

Diffuse over most of gaiter area (lower 1/3) or recent pigmentation (purple)

Wider distribution (above lower 1/3), recent pigmentation

INFLAMMATION

None

Mild cellulitis, limited to marginal area around ulcer

Moderate cellulitis, involves most of gaiter area (lower 2/3)

Severe cellulitis (lower 1/3 and above) or significant venous eczema

INDURATION

None

Focal, circum-malleolar (<5 cm)

Medial or lateral, less than lower 1/3 of leg

Entire lower 1/3 of leg or more

ACTIVE ULCERS, N

0

1

2

>2

ACTIVE ULCERATION DURATION (longest duration; if 3 months, select >3 months)

None

<3 months

>3 months, <1year

Not healed >1 year

ACTIVE ULCER, SIZE (largest ulcer)

None

<2 cm diameter

2-6 cm diameter

>6 cm diameter

COMPRESSIVE THERAPY

Not used or not compliant

Intermittent use of stockings

Wears elastic stockings most days

Full compliance: stockings + elevation

BRIEF CLINICAL HISTORY

	Yes	No
Previous history of DVT	<input type="checkbox"/>	<input type="checkbox"/>

If yes, give details

	Yes	No
Previous treatment of varicose veins to contra-lateral leg	<input type="checkbox"/>	<input type="checkbox"/>

If yes, type of treatment:

Laser treatment	<input type="checkbox"/>
Surgery	<input type="checkbox"/>
Foam sclerotherapy	<input type="checkbox"/>

	Yes	No
Previous foam sclerotherapy or sclerotherapy to tributaries of study leg	<input type="checkbox"/>	<input type="checkbox"/>

Duplex scan of study leg

Reflux >1s at the following sites	Yes	No	Not examined
Groin - long saphenous origin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deep vein just below SF junction (common femoral / superficial vein)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid thigh - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Popliteal fossa - short saphenous origin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Popliteal vein (below SP junction)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid calf - short saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diameter of trunk vein

Widest diameter below sapheno-femoral junction	<input type="text" value="mm"/>	Not measured <input type="checkbox"/>
Widest diameter below sapheno-popliteal junction	<input type="text" value="mm"/>	<input type="checkbox"/>

Summary of vein involvement on study leg

Long saphenous Yes No

Short saphenous Yes No

Date of scan

/ /

Name of person performing
duplex scan

Comments on scan, including
tortuosity, depth

CRITERIA FOR STUDY ENTRY

(all criteria must be fulfilled)

Study leg:

Must have primary varicose veins

CEAP grade 2 or above

Size of vein: greater than 3mm and less than 15mm

1 second reflux present

Must be suitable for laser treatment - vein depth

Must be suitable for laser treatment - tortuosity

RANDOMISATION

Date of randomisation

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

TREATMENT ALLOCATION

Surgery

Foam sclerotherapy

Laser therapy

Name of person undertaking randomisation

HEIGHT & WEIGHT

Height (in cm)

Weight (in kg)

EMPLOYMENT STATUS

Self-employed

An employee

Other

→ Please specify below

PHYSICAL ACTIVITY

Type and amount of physical activity involved in your work (mark one box only)

I am not in employment (e.g. retired, retired for health reasons, unemployed, full-time carer etc)

I spend most of my time at work sitting (such as in an office)

I spend most of my time at work standing or walking. However, my work does not require much intense physical effort (e.g. shop assistant, hairdresser, security guard, childminder etc.)

My work involves definite physical effort including handling of heavy objects and use of tools (e.g. plumber, electrician, carpenter, cleaner, hospital nurse, gardener, postal delivery workers etc)

My work involves vigorous physical activity including handling of very heavy objects (e.g. scaffolder, construction worker, refuse collector, etc.)

During the last week, how many hours did you spend on each of the following activities? (mark one box on each row)

	None	Some but less than 1 hour	1 hour but less than 3 hours	3 hours or more
Physical exercise such as swimming, jogging, aerobics, football, tennis, gym workout etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cycling, including cycling to work and during leisure time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking, including walking to work, shopping, for pleasure etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Housework/childcare	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gardening/DIY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

How would you describe your usual walking pace? (mark one box only)

Slow pace
(i.e. less than 3 mph)

Steady average pace

Brisk pace

Fast pace
(i.e. over 4 mph)



Comparison of LAser, Surgery
and foam Sclerotherapy

PRESENCE OF VARICOSE VEINS

Study Number

--	--	--	--	--	--

STUDY LEG

Right leg

Left leg

We would like to know how you see the amount of varicose veins on your leg.
On the scale below, please indicate how many varicose veins you think you have.

No varicose veins									The most varicose veins I can imagine

For office use only:

Completed by:

Participant

Research nurse

Timepoint:

Baseline

Six weeks

Six months

NB: the participant and research nurse should complete this independently.

Study Number

--	--	--	--	--	--

CLASS

Comparison of **LA**ser, **S**urgery and foam **S**clerotherapy

Confidential

Thank you for helping us with our research.
We would be very grateful if you could complete this
questionnaire.

SECTION A: DESCRIBING YOUR OWN HEALTH TODAY – (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

- | | | |
|---|--|--------------------------|
| A1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| A2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| A3. Usual Activities
<i>(e.g. work, study, housework, family or leisure activities)</i> | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| A4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| A5. Anxiety/Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

*Best imaginable
health state*

100

A6. Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box below to the point on the scale that best indicates how good or bad your health state is today

Your
health
state
today

90

80

70

60

50

40

30

20

10

0

*Worst imaginable
health state*

SECTION B: YOUR GENERAL HEALTH (SF-36)

Please fill in all the questions by crossing the relevant box of the answer that applies to you.

These questions ask for your views about your health and how you feel about life in general. Do not spend too much time in answering as your immediate response is likely to be the most accurate, but please make sure you answer every question.

B1. In general, would you say your health is?

Excellent

Very good

Good

Fair

Poor

B2. Compared to one year ago, how would you rate your health in general now?

Much better
now than one
year ago

Somewhat better
now than one
year ago

About the
same as
one year ago

Somewhat worse
now than one
year ago

Much worse
now than one
year ago

B3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities , such as running, lifting heavy objects, participating in strenuous sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Walking more than one mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Walking several hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Bathing and dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B8. During the past 4 weeks, how much did pain interfere with your normal work (including both outside the home and housework)?

Not at all

A little bit

Moderately

Quite a bit

Extremely

B9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Did you feel full of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Have you been very nervous?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Have you felt downhearted and depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Did you feel worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Have you been happy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc)?

All of the time

Most of the time

Some of the time

A little of the time

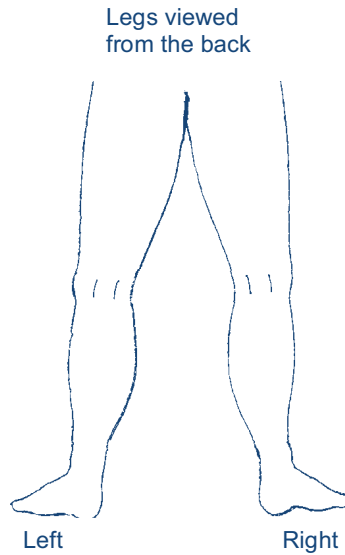
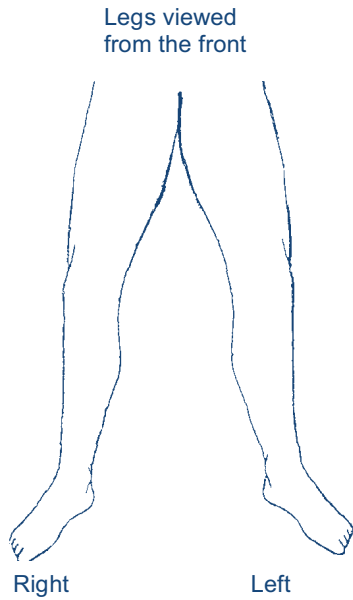
None of the time

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anyone I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION C: YOUR VARICOSE VEINS

C1. Please draw in your varicose veins in the diagram(s) below:-



C2. In the last two weeks, for how many days did your varicose veins cause you pain or ache? (Please cross one box for each leg)

	Right Leg	Left Leg
None at all	<input type="checkbox"/>	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>	<input type="checkbox"/>

C3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins? (Please cross one box)

None at all	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>

C4. In the last two weeks, how much ankle swelling have you had? (Please cross one box)

None at all	<input type="checkbox"/>
Slight ankle swelling	<input type="checkbox"/>
Moderate ankle swelling (causing you to sit with your feet up whenever possible)	<input type="checkbox"/>
Severe ankle swelling (causing you difficulty putting on your shoes)	<input type="checkbox"/>

C5. In the last two weeks, have you worn support stockings or tights? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those I bought myself without a doctor's prescription	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear occasionally	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear every day	<input type="checkbox"/>	<input type="checkbox"/>

C6. In the last two weeks, have you had any itching in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only above the knee	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only below the knee	<input type="checkbox"/>	<input type="checkbox"/>
Both above and below the knee	<input type="checkbox"/>	<input type="checkbox"/>

C7. Do you have any purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C8. Do you have a rash or eczema in the area of your ankle? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but it does not require any treatment from a doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>
Yes, and it requires treatment from my doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>

C9. Do you have a skin ulcer associated with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C10. Does the appearance of your varicose veins cause you concern? (Please cross one box)

No	<input type="checkbox"/>
Yes, their appearance causes me slight concern	<input type="checkbox"/>
Yes, their appearance causes me moderate concern	<input type="checkbox"/>
Yes, their appearance causes me a great deal of concern	<input type="checkbox"/>

C11. Does the appearance of your varicose veins influence your choice of clothing including tights? (Please cross one box)

- No
- Occasionally
- Often
- Always

C12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities? (Please cross one box)

- No
- I have been able to work but my work has suffered to a slight extent
- I have been able to work but my work has suffered to a moderate extent
- My veins have prevented me from working one day or more

C13. During the last two weeks have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)? (Please cross one box)

- No
- Yes, my enjoyment has suffered to a slight extent
- Yes, my enjoyment has suffered to a moderate extent
- Yes, my veins have prevented me taking part in any leisure activities

SECTION D: YOUR SYMPTOMS

Listed below are a number of symptoms that you may or may not have experienced since you developed varicose veins.

Please indicate by crossing **Yes** or **No** whether you have experienced any of these symptoms since you developed varicose veins, and whether you believe that these symptoms are related to your varicose veins.

		I have experienced this symptom since I developed varicose veins		This symptom is related to my varicose veins					
D1.	Pain	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D2.	Hardening of the skin on the legs	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D3.	Redness of the skin on the legs	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D4.	Sleep difficulties	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D5.	Swelling of the ankle	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D6.	Discolouration or brown staining on the leg	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D7.	Stiff joints	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D8.	Weight loss	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D9.	Dizziness	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D10.	Fatigue	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D11.	Breaks in the skin or ulcers on the leg	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D12.	Sore eyes	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D13.	Breathlessness	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
D14.	Loss of strength	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

SECTION E: YOUR VIEWS ABOUT YOUR VARICOSE VEINS

We are interested in your own personal views of how you now see your varicose veins. Please indicate how much you agree or disagree with the following statements about your varicose veins by crossing the appropriate box.

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E1. My varicose veins will last a short time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E2. My varicose veins are likely to be permanent rather than temporary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E3. My varicose veins will last for a long time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E4. These varicose veins will pass quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E5. I expect to have these varicose veins for the rest of my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E6. My varicose veins are a serious condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E7. My varicose veins have major consequences on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E8. My varicose veins do not have much effect on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E9. My varicose veins strongly affect the way others see me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E10. My varicose veins have serious financial consequences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E11. My varicose veins cause difficulties for those who are close to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E12. There is a lot which I can do to control my symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E13. What I do can determine whether my varicose veins get better or worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E14. The course of my varicose veins depends on me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E15. Nothing I do will affect my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E16. I have the power to influence my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E17. My actions will have no effect on the outcome of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E18. My varicose veins will improve in time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E19. There is very little that can be done to improve my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E20. My treatment will be effective in curing my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E21. The negative effects of my varicose veins can be prevented (avoided) by my treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E22. My treatment can control my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E23. There is nothing which can help my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E24. The symptoms of my varicose veins are puzzling to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E25. My varicose veins are a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E26. I don't understand my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E27. My varicose veins don't make any sense to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E28. I have a clear picture or understanding of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E29. The symptoms of my varicose veins change a great deal from day to day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E30. My symptoms come and go in cycles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E31. My varicose veins are very unpredictable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E32. I go through cycles in which my varicose veins get better and worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E33. I get depressed when I think about my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E34. When I think about my varicose veins I get upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E35. My varicose veins make me feel angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E36. My varicose veins do not worry me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E37. Having these varicose veins makes me feel anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E38. My varicose veins make me feel afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION F: CAUSES OF YOUR VARICOSE VEINS

We are interested in what you consider may have been the cause of your varicose veins. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your varicose veins rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your varicose veins. Please indicate how much you agree or disagree that they were causes for you by crossing the appropriate box.

Possible causes	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
F1. Stress or worry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F2. Hereditary - it runs in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F3. A germ or virus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F4. Diet or eating habits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F5. Chance or bad luck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F6. Poor medical care in my past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F7. Pollution in the environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F8. My own behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F9. My mental attitude, e.g. thinking about life negatively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F10. Family problems or worries caused my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F11. Overwork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F12. My emotional state, e.g. feeling down, lonely, anxious, empty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F13. Ageing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F14. Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F15. Smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F16. Accident or injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F17. My personality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F18. Altered immunity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the table below, please list in rank-order the three most important factors that you now believe caused your varicose veins. You may use any of the items from the previous page, or you may have additional ideas of your own.

The most important causes for me:-

1. _____

2. _____

3. _____

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire. Please hand the questionnaire back to the research nurse or return it in the enclosed reply-paid envelope to the Trial Office in Aberdeen.

The information you have given us will be extremely useful in helping us carry out research. It will be treated with the strictest confidence and kept securely.

Thank you again for your help

If you would like any further information or have any queries about the study,
please contact:

The CLASS Trial Office in Aberdeen (Tel: 01224 XXXXXX)

This study is taking place across the UK but the questionnaires are being processed in Aberdeen at The Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.

Reminder letter to participants who do not return baseline questionnaire

Date

<<Title>> <<Name>> << Surname>>

Study No.

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>«Address3»

<<Postcode>>«Address4»

Dear <<Title>> <<Surname>>

Title of Study:

Thank you very much for taking part in the XXX Study.

When you attended your appointment with the research nurse recently, we gave you a questionnaire to take home and complete. Unfortunately we have not yet received it back from you (if it is in the post, sorry to bother you and please ignore this reminder).

We are keen to find out how you are before your varicose veins are treated. It is very important for the success of the study that we have as much information as possible about you.

Some of the questions may not seem relevant but we would be very grateful if you could try to fill them all in. If you have any problems in completing the questionnaires, a friend or relative may be able to help you. Alternatively, please contact the CLASS Study Office; we will be happy to help in any way we can.

Please return the questionnaire in the reply-paid envelope provided.

In the meantime, if you require any further help or information about the Study, please contact the Study office.

Yours sincerely

Letter to participant confirming what treatment they have been randomised to

Date

<<Title>> <<Name>> << Surname>>

Study No.

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>«Address3»

<<Postcode>>«Address4»

Dear <<Title>> <<Surname>>

Title of Study:

Thank you very much for taking part in the CLASS Study.

You should have received an appointment for the treatment of your varicose veins. This will have been sent direct from the hospital. If you have not received an appointment, please do get in touch with the CLASS study office. The treatment you have been allocated is xxx. You can read more about the treatment in the leaflet on varicose veins and treatment that you received from the CLASS study. If you would like another copy of this leaflet, please get in touch with us and we can send one to you.

We enclose a questionnaire as we are keen to find out whether your views on your varicose veins have changed since you agreed to take part in the study.

Some of the questions may not seem relevant but we would be very grateful if you could try to fill them all in. If you have any problems in completing the questionnaires, a friend or relative may be able to help you. Alternatively, please contact the CLASS Study Office; we will be happy to help in any way we can.

Please return the questionnaire in the reply-paid envelope provided.

If you have any questions, or require any further information about the Study, please contact the Study office.

Yours sincerely

Letter to GP informing them of their patient's participation in CLASS

Date

Dr <<GP Name>> << GP Surname>>
<<GP Address 1>>
<<GP Address 2>>
<<GP Address 3>>
<<GP Address 4>>«Address3»
<<GP Postcode>>«Address4»

Dear Dr <<Surname>>

Patient Details <<title >> <<Name>> << Surname>>

Date of birth: <<dob>>

Address: <<patient address>>

Title of Study: RANDOMISED CONTROLLED TRIAL COMPARING FOAM SCLEROTHERAPY, ALONE OR IN COMBINATION WITH ENDOVENOUS LASER THERAPY, WITH CONVENTIONAL SURGERY AS TREATMENT FOR VARICOSE VEINS

Vascular Surgeons: [*insert names of local surgeons*]

Your patient has agreed to take part in this study. This is a major research study funded by the Health Technology Assessment (HTA) programme of the NHS, taking place in [*insert site*] and in five other sites throughout the UK. It is comparing three different kinds of treatments for varicose veins - conventional surgery, foam sclerotherapy and endovenous laser therapy in terms of their clinical and cost-effectiveness.

Patients receive written information regarding the study and the various treatment options at their initial out-patient clinic visit and are then contacted to ask if they wish to take part. If they agree they attend to provide consent and to have a full baseline assessment. They are then randomised to one of the treatments. Following treatment, patients will be followed up at 6 weeks and 6 months at a clinic appointment for clinical examination, a duplex scan and completion of a questionnaire.

I hope that you would be in accord with your patient participating in this study. The aim is to provide robust data to guide the treatment of varicose veins. Your patient will have been given clear written information about the potential benefits and disadvantages of the trial and we will only involve them after fully informed consent. Please do not hesitate to contact me if you have any concerns about your patient being included in this study.

With best wishes,

Yours sincerely

Letter to GP informing them of the treatment to which the patient has been randomised

Date

Dr <<GP Name>> << GP Surname>>
<<GP Address 1>>
<<GP Address 2>>
<<GP Address 3>>
<<GP Address 4>>«Address3»
<<GP Postcode>>«Address4»

Dear Dr <<Surname>>

Patient Details <<title >> <<Name>> << Surname>>

Date of birth: <<dob>>

Address: <<patient address>>

***Title of Study:* RANDOMISED CONTROLLED TRIAL COMPARING FOAM SCLEROTHERAPY, ALONE OR IN COMBINATION WITH ENDOVENOUS LASER THERAPY, WITH CONVENTIONAL SURGERY AS TREATMENT FOR VARICOSE VEINS**

Vascular surgeons: *[insert names of local surgeons]*

As you know from our previous letter, your patient has agreed to take part in this study. This is a major research study funded by the Health Technology Assessment (HTA) programme of the NHS, taking place in six sites throughout the UK. It is comparing three different kinds of treatments for varicose veins - conventional surgery, foam sclerotherapy and endovenous laser therapy in terms of their clinical and cost-effectiveness.

Your patient has been randomised to receive <<treatment allocation>>, and, if they have not already received an appointment for this, they will receive one shortly.

Please do not hesitate to contact me if you have any concerns about your patient being included in this study.

With best wishes,

Yours sincerely

Study Number

--	--	--	--	--	--	--

CLASS

Comparison of **LA**ser, **S**urgery and foam **S**clerotherapy

Confidential

Thank you for helping us with our research.
We would be very grateful if you could complete this
questionnaire.

SECTION A: YOUR SYMPTOMS

Listed below are a number of symptoms that you may or may not have experienced since you developed varicose veins.

Please indicate by ticking **Yes** or **No** whether you have experienced any of these symptoms since you developed varicose veins, and whether you believe that these symptoms are related to your varicose veins.

	I have experienced this symptom since I developed varicose veins		This symptom is related to my varicose veins	
A1. Pain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A2. Hardening of the skin on the legs	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A3. Redness of the skin on the legs	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A4. Sleep difficulties	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A5. Swelling of the ankle	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A6. Discolouration or brown staining on the leg	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A7. Stiff joints	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A8. Weight loss	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A9. Dizziness	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A10. Fatigue	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A11. Breaks in the skin or ulcers on the leg	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A12. Sore eyes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A13. Breathlessness	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
A14. Loss of strength	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

SECTION B: YOUR VIEWS ABOUT YOUR VARICOSE VEINS

We are interested in your own personal views of how you now see your varicose veins. Please indicate how much you agree or disagree with the following statements about your varicose veins by ticking the appropriate box.

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B1. My varicose veins will last a short time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B2. My varicose veins are likely to be permanent rather than temporary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B3. My varicose veins will last for a long time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B4. These varicose veins will pass quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B5. I expect to have these varicose veins for the rest of my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B6. My varicose veins are a serious condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B7. My varicose veins have major consequences on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B8. My varicose veins do not have much effect on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B9. My varicose veins strongly affect the way others see me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B10. My varicose veins have serious financial consequences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B11. My varicose veins cause difficulties for those who are close to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B12. There is a lot which I can do to control my symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B13. What I do can determine whether my varicose veins get better or worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B14. The course of my varicose veins depends on me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B15. Nothing I do will affect my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B16. I have the power to influence my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B17. My actions will have no effect on the outcome of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B18. My varicose veins will improve in time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B19. There is very little that can be done to improve my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B20. My treatment will be effective in curing my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B21. The negative effects of my varicose veins can be prevented (avoided) by my treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B22. My treatment can control my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B23. There is nothing which can help my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B24. The symptoms of my varicose veins are puzzling to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B25. My varicose veins are a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B26. I don't understand my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B27. My varicose veins don't make any sense to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B28. I have a clear picture or understanding of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B29. The symptoms of my varicose veins change a great deal from day to day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B30. My symptoms come and go in cycles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B31. My varicose veins are very unpredictable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B32. I go through cycles in which my varicose veins get better and worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B33. I get depressed when I think about my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B34. When I think about my varicose veins I get upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B35. My varicose veins make me feel angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B36. My varicose veins do not worry me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B37. Having these varicose veins makes me feel anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B38. My varicose veins make me feel afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION C: CAUSES OF YOUR VARICOSE VEINS

We are interested in what you consider may have been the cause of your varicose veins. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your varicose veins rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your varicose veins. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

Possible causes	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
C1. Stress or worry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C2. Hereditary - it runs in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C3. A germ or virus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C4. Diet or eating habits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C5. Chance or bad luck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C6. Poor medical care in my past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C7. Pollution in the environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C8. My own behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C9. My mental attitude, e.g. thinking about life negatively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C10. Family problems or worries caused my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C11. Overwork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C12. My emotional state, e.g. feeling down, lonely, anxious, empty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C13. Ageing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C14. Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C15. Smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C16. Accident or injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C17. My personality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C18. Altered immunity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the table below, please list in rank-order the three most important factors that you now believe caused your varicose veins. You may use any of the items from the previous page, or you may have additional ideas of your own.

The most important causes for me:-

1. _____

2. _____

3. _____

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire. Please hand the questionnaire back to the research nurse or return it in the enclosed reply-paid envelope to the Trial Office in Aberdeen.

The information you have given us will be extremely useful in helping us carry out research. It will be treated with the strictest confidence and kept securely.

Thank you again for your help

If you would like any further information or have any queries about the study, please contact:

The CLASS Trial Office in Aberdeen (Tel: 01224 XXXXXX)

This study is taking place across the UK but the questionnaires are being processed in Aberdeen at The Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.

Comparison of LAsER, Surgery and foam Sclerotherapy

Study Number

Study leg

Right

Left

(defined at baseline; in bilateral cases study leg designated as worst affected leg **by patient**)

Date of surgery

/ /

Confirmation that patient is eligible for treatment:

A: Vein - exclusion criteria

- CEAP 0/1, non-symptomatic
- Reflux <1 second
- Current deep vein thrombosis
- Acute superficial vein thrombosis
- Long or short saphenous vein less than 3mm in diameter or greater than 15mm
- Tortuous veins that are considered to be unsuitable for EVLA due to difficulties in passing the guide wire

Eligible

Not eligible

B: Patient co-morbidity - exclusion criteria

- Cardiac failure
- Pulmonary oedema
- Local or systemic infection
- Pregnancy or breast feeding
- History of hypercoagulability
- Inability to mobilise post-procedure
- Varicosities caused by pelvic or abdominal tumours
- Arterial disease (ankle brachial pressure index <0.8)
- Patients who are not fit for a general anaesthetic due to significant systemic disease, morbid obesity or other causes.

Eligible

Not eligible

If patient is not eligible for treatment they should not be treated in CLASS

Was the participant randomised to receive SURGERY?

Yes

No

If No, please give reason why the participant is receiving SURGERY

Details of treatment to study leg

Long saphenous vein

Yes

No

If yes:

Stripping to

Above knee

Below knee

Phlebectomies

Yes

No

Short saphenous vein

Yes

No

If yes:

Stripping to

Below knee

Phlebectomies

Yes

No

Grade of surgeon

Consultant

Staff grade

Trainee

Supervised by consultant Yes No

Supervised by consultant Yes No

Grade of anaesthetist present

Consultant	<input type="checkbox"/>	Associate specialist	<input type="checkbox"/>
Staff grade	<input type="checkbox"/>	Registrar	<input type="checkbox"/>
SHO	<input type="checkbox"/>		

Type of anaesthesia

General	<input type="checkbox"/>	Epidural/spinal	<input type="checkbox"/>
SC HEPARIN or derivative	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
HRT	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Oral contraceptive	Yes <input type="checkbox"/>	No	<input type="checkbox"/>

Timings

Please use 24 hour clock

Time of entry into anaesthetic room

	H	H	:	m	m
<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>

Operating time
(time between starting preparation of the patient and finishing bandaging)

Time of starting preparation of patient	H	H	:	m	m
Time of finishing bandaging	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
Time of leaving operating room	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
Time of leaving recovery room	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>

Was planned treatment completed?

Yes No

If No, give reason

Contra-lateral leg

Was contra-lateral leg treated at same time? Yes No

Stocking/bandage to study leg

Length Full Knee

Make / grade

Recommended duration according to protocol (10 days) Yes No

If No: recommended duration Days

Reason for duration of bandaging not 10 days

Procedural complications (before discharge)

Procedural complications Yes No

If yes, give details below:

Wound haematoma Yes No
If Yes:

Required drainage Yes No

Required overnight stay Yes No

Bleeding Yes No
If Yes:

Required overnight stay Yes No

Damage to major artery* Yes No

If yes: Common femoral Superficial femoral Popliteal

Damage to major vein* Yes No

If yes: Common femoral Popliteal

Damage to major nerve* Yes No

If yes: Femoral Tibial Peroneal

Other Yes No

If yes, give details

* Details of these should also be reported as a Serious Adverse Event.

Anaesthetic side effects

Anaesthetic side effects Yes No

If yes, give details below:

Blurred vision Yes No

Sickness Yes No

Muscle pains Yes No

Headache Yes No

Sore throat Yes No

Damage to teeth, lip or tongue Yes No

Allergic/anaphylactoid reactions Yes No

Other Yes No

If yes, give details

Time in hospital

Planned day-case Yes No

Planned overnight stay Yes No

Unexpected overnight stay Yes No

Reason for admission

Date admitted to hospital

Date discharged from hospital



FOAM SCLEROTHERAPY

Comparison of LAser, Surgery
and foam Sclerotherapy

Study Number

--	--	--	--	--	--

Study leg

Right

Left

(defined at baseline; in bilateral cases study leg designated as worst affected leg **by patient**)

Date of foam sclerotherapy

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Confirmation that patient is eligible for treatment:

A: Vein - exclusion criteria

- CEAP 0/1, non-symptomatic
- Reflux <1 second
- Current deep vein thrombosis
- Acute superficial vein thrombosis
- Long or short saphenous vein less than 3mm in diameter or greater than 15mm
- Tortuous veins that are considered to be unsuitable for EVLA due to difficulties in passing the guide wire

Eligible

Not eligible

B: Patient co-morbidity - exclusion criteria

- Cardiac failure
- Pulmonary oedema
- Local or systemic infection
- Pregnancy or breast feeding
- History of hypercoagulability
- Inability to mobilise post-procedure
- Varicosities caused by pelvic or abdominal tumours
- Arterial disease (ankle brachial pressure index <0.8)
- Patients who are not fit for a general anaesthetic due to significant systemic disease, morbid obesity or other causes.

Eligible

Not eligible

C: Other

- Allergy to sclerosant.

Eligible

Not eligible

If patient is not eligible for treatment they should not be treated in CLASS

Is the patient receiving foam sclerotherapy in accordance with their randomisation (i.e. they were randomised to FOAM SCLEROTHERAPY, or were randomised to EVLA and are receiving foam following EVLA)?

Yes

No

If No, please give reason why the participant is receiving FOAM SCLEROTHERAPY?

--

Details of treatment to study leg

Long saphenous vein

Yes

No

If yes, Confirm

Fibrovein

Fibrovein:air ratio 1:3

3%

Manufacturer's lot/batch number

Expiry date

 / /

Total volume of foam

 ml

Short saphenous vein

Yes

No

If yes, Confirm

Fibrovein

Fibrovein:air ratio 1:3

3%

Manufacturer's lot/batch number

As above

Expiry date

 / /

As above

Total volume of foam

 ml

Non-truncal varicosites

Yes - calf

Yes - thigh

No

If yes, Confirm

Fibrovein

Fibrovein:air ratio 1:3

1%

Manufacturer's lot/batch number

Expiry date

 / /

Total volume of foam

 ml

Local anaesthetic

Yes No

If yes: Type of anaesthetic

Concentration

Volume

SC HEPARIN or derivative

Yes No

HRT

Yes No

Oral contraceptive

Yes No

Grade of surgeon performing treatment

Consultant

Staff grade Supervised by consultant Yes No

Trainee Supervised by consultant Yes No

Consultant nurse Supervised by consultant Yes No

Duration

Please use 24 hour clock

H H m m

Time of entry into treatment room :

Treatment time

Time of start (preparation of patient) :

Time of finish (completion of bandaging) :

Time of leaving treatment room :

Was planned treatment completed? Yes No

If No, give reason

Stocking/bandage to study leg

Confirm that bandaging according to protocol -
Velband/PehaHaft/Credelast stockings, for ten days

Yes

No

If not according to protocol:

Type of bandaging applied

Recommended duration

Reason why bandaging not according
to protocol

Contra-lateral leg

Was contra-lateral leg treated at same time?

Yes

No

Procedural complications (noted at time of treatment)

Procedural complications

Yes

No

If yes, give details below:

Visual disturbance

Yes

No

If yes, give details

Headache

Yes

No

If yes,

migraine with aura

headache

Transient confusion

Yes

No

If yes, give details/duration

Panic attack

Yes

No

If yes, give details/duration

Malaise

Yes

No

If yes, give details/duration

Cough

Yes

No

If yes, give details/duration

Chest tightness/heaviness

Yes

No

If yes, give details/duration

Vasovagal

Yes

No

If yes, give details/duration

Extravasation of foam

Yes

No

If yes, give details

Anaphylacoid reaction*

Yes

No

If yes, give details

Stroke*

Yes

No

If yes, state hemisphere and Rankin grade

Transient ischaemic attack[†]

Yes

No

If yes, give details

Myocardial infarction*

Yes

No

If yes, give details

Intra-arterial injection*

Yes

No

If yes, give details

Epileptic fit*

Yes

No

If yes, give details/duration

Other

Yes

No

If yes, give details

*** Details of these should also be reported as a Serious Adverse Event.
Permanent loss of vision should also be reported as a Serious Adverse Event.
† If hospitalised after transient ischaemic attack or other complication, this should also be reported as a serious adverse event.**

Hospital admission

Was the patient admitted to hospital immediately after the procedure?

Yes No

If yes:

Reason for admission

Date of admission

 / /

Date of discharge

 / /



LASER THERAPY

Comparison of LASer, Surgery and foam Sclerotherapy

Study Number

--	--	--	--	--	--

Study leg

Right

Left

(defined at baseline; in bilateral cases study leg designated as worst affected leg **by patient**)

Date of laser therapy

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Confirmation that patient is eligible for treatment:

A: Vein - exclusion criteria

- CEAP 0/1, non-symptomatic
- Reflux <1 second
- Current deep vein thrombosis
- Acute superficial vein thrombosis
- Long or short saphenous vein less than 3mm in diameter or greater than 15mm
- Tortuous veins that are considered to be unsuitable for EVLA due to difficulties in passing the guide wire

Eligible

Not eligible

B: Patient co-morbidity - exclusion criteria

- Cardiac failure
- Pulmonary oedema
- Local or systemic infection
- Pregnancy or breast feeding
- History of hypercoagulability
- Inability to mobilise post-procedure
- Varicosities caused by pelvic or abdominal tumours
- Arterial disease (ankle brachial pressure index <0.8)
- Patients who are not fit for a general anaesthetic due to significant systemic disease, morbid obesity or other causes.

Eligible

Not eligible

If patient is not eligible for treatment they should not be treated in CLASS

Was the participant randomised to receive LASER THERAPY?

Yes

No

If No, please give reason why the participant is receiving LASER THERAPY

--

Details of treatment to study leg

Long saphenous vein

Yes

No

If Yes:

Cannulation Above knee

Below knee

Laser delivery Continuous

Interrupted

Watts

Joules

Length (cm)

Joules/cm

Laser type/wavelength

Plebectomies Yes No

N/A (Centres other than Hull)

Short saphenous vein

Yes

No

If Yes:

Cannulation Above knee

Below knee

Laser delivery Continuous

Interrupted

Watts

Joules

Length (cm)

Joules/cm

Laser type/wavelength

Plebectomies Yes No

N/A (Centres other than Hull)

Local anaesthetic to study leg

Skin

Yes No

If yes: Type

Concentration

Tumescent

Yes No

If yes: Cooled

Yes No

Volume of tumescent

 ml

Anaesthetic added to
Tumescent

Yes No

Type of anaesthetic

Concentration

Sedation

Yes No

If yes: Give details

SC HEPARIN or derivative

Yes No

HRT

Yes No

Oral contraceptive

Yes No

Grade of surgeon performing laser therapy

Consultant

Staff grade Supervised by consultant Yes No

Trainee Supervised by consultant Yes No

Duration

Please use 24 hour clock

Time of entry into treatment room

H	H	:	m	m
<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>

Treatment time

Time of start (preparation of patient)

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
----------------------	----------------------	---	----------------------	----------------------

Time of finish (completion of bandaging)

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
----------------------	----------------------	---	----------------------	----------------------

Time of leaving treatment room

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
----------------------	----------------------	---	----------------------	----------------------

Was planned treatment completed?

Yes

No

If No, give reason

Stocking/bandage

Length

Full

Knee

Make / grade

Recommended duration according to protocol (10 days)

Yes

No

If No: recommended duration

days

Reason for duration of bandaging not 10 days

Contra-lateral leg

Was contra-lateral leg treated at same time?

Yes

No

Procedural complications (noted at time of treatment)

Procedural complications Yes No

If yes, give details below:

Wound haematoma Yes No
If yes:

Required drainage Yes No

Required overnight stay Yes No

Damage to major vein* Yes No

If yes: Femoral Popliteal

Other Yes No

If yes, give details

***Details of these should also be reported as a serious adverse event**

Hospital admission

Was the patient admitted to hospital immediately after the procedure?

Yes No

If yes:

Reason for admission

Date of admission / /

Date of discharge / /



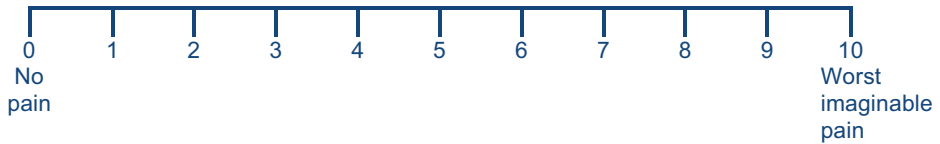
Comparison of LAser, Surgery
and foam Sclerotherapy

PAIN DURING TREATMENT

Study Number

--	--	--	--	--	--

Please rate the worst pain that you experienced while you were having your treatment. The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a cross (X) on the line that best indicates the rating of the pain you experienced while you were having your treatment for varicose veins.





Comparison of LAser, Surgery
and foam Sclerotherapy

6 WEEK ASSESSMENT

Study Number

STUDY LEG

Right

Left

Date of 6 week assessment

 / /

DUPLEX SCAN Complete for study leg only

	Not examined	Complete occlusion (absent)	Partial occlusion	No occlusion (patent)	If patent, is reflux	
					Present	Absent
Groin - long saphenous (flush with CFV - ie within 1cm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Groin - long saphenous (within 3cm of CFV)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Common femoral/superficial vein*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid thigh - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short saphenous (flush with popliteal - i.e. within 1cm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short saphenous (within 3cm of popliteal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Popliteal vein*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid calf - short saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Occlusion in the common femoral vein or popliteal fossa-popliteal vein (DVT) should be reported as a Serious Adverse Event (if not already reported)

Name of person performing duplex scan

Date of duplex scan

 / /

CEAP CLASSIFICATION

Complete for **study leg only** - Please tick appropriate response

- C0 No visible or palpable signs of venous disease.
- C1 Telangiectasis or reticular veins. Veins less than 3 mm
- C2 Varicose veins. Veins over 3 mm
- C3 Edema
- C4 Skin and subcutaneous changes
- C4a Pigmentation or eczema
- C4b Lipodermatosclerosis or atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer

VENOUS CLINICAL SEVERITY SCORE (VCSS)

Complete for study leg only

PAIN

- | | | | |
|-------------------------------|---|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Occasional, not restricting activity or requiring analgesics | <input type="checkbox"/> Daily, moderate activity limitation, occasional analgesics | <input type="checkbox"/> Daily, severe limiting activities or requiring regular use of analgesics |
|-------------------------------|---|---|---|

VARICOSE VEINS i.e. >3mm

- | | | | |
|-------------------------------|---|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Few, scattered branch varicose veins | <input type="checkbox"/> Multiple: GSV varicose veins confined to calf or thigh | <input type="checkbox"/> Extensive: thigh and calf or GSV and SSV distribution |
|-------------------------------|---|---|--|

VENOUS EDEMA

- | | | | |
|-------------------------------|---|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Evening ankle only | <input type="checkbox"/> Afternoon edema, above ankle | <input type="checkbox"/> Morning edema above ankle and requiring activity change, elevation |
|-------------------------------|---|---|---|

SKIN PIGMENTATION

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> None or focal, low intensity (tan) | <input type="checkbox"/> Diffuse, but limited in area and old (brown) | <input type="checkbox"/> Diffuse over most of gaiter area (lower 1/3) or recent pigmentation (purple) | <input type="checkbox"/> Wider distribution (above lower 1/3), recent pigmentation |
|---|---|---|--|

INFLAMMATION

- | | | | |
|-------------------------------|---|--|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Mild cellulitis, limited to marginal area around ulcer | <input type="checkbox"/> Moderate cellulitis, involves most of gaiter area (lower 2/3) | <input type="checkbox"/> Severe cellulitis (lower 1/3 and above) or significant venous eczema |
|-------------------------------|---|--|---|

INDURATION

- | | | | |
|-------------------------------|--|--|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Focal, circum-malleolar (<5 cm) | <input type="checkbox"/> Medial or lateral, less than lower 1/3 of leg | <input type="checkbox"/> Entire lower 1/3 of leg or more |
|-------------------------------|--|--|--|

ACTIVE ULCERS, N

- | | | | |
|----------------------------|----------------------------|----------------------------|-----------------------------|
| <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> >2 |
|----------------------------|----------------------------|----------------------------|-----------------------------|

ACTIVE ULCERATION DURATION

- | | | | |
|-------------------------------|------------------------------------|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> <3 months | <input type="checkbox"/> >3 months, <1 year | <input type="checkbox"/> Not healed >1 year |
|-------------------------------|------------------------------------|---|---|

ACTIVE ULCER, SIZE

- | | | | |
|-------------------------------|---|--|---|
| <input type="checkbox"/> None | <input type="checkbox"/> <2 cm diameter | <input type="checkbox"/> 2-6 cm diameter | <input type="checkbox"/> >6 cm diameter |
|-------------------------------|---|--|---|

COMPRESSIVE THERAPY

- | | | | |
|--|--|--|---|
| <input type="checkbox"/> Not used or not compliant | <input type="checkbox"/> Intermittent use of stockings | <input type="checkbox"/> Wears elastic stockings most days | <input type="checkbox"/> Full compliance: stockings + elevation |
|--|--|--|---|

COMPLICATIONS

Numbness

Yes No

If yes: state distribution/dimensions

Persistent bruising

Yes No

If yes: state distribution/dimensions

Persistent tenderness/discomfort

Yes No

If yes: state distribution/dimensions

Skin loss/ulceration

Yes No

If yes: state distribution/dimensions

Lumpiness

Yes No

If yes: state distribution/dimensions

Development of thread vein

Yes No

If yes: state distribution/dimensions

Skin staining

Yes No

If yes: state distribution/dimensions

Wound infection

Yes No

If yes:

Required antibiotics

Yes No

Required drainage

Yes No

Required hospital admission

Yes No

Back-ache

Yes No

If yes: give details

Headache

Yes No

If yes: give details

Deep vein thrombosis*

Yes No

If yes: state distribution/dimensions

Pulmonary embolus*

Yes

No

If yes: give details of severity

Stroke*

Yes

No

If yes: state hemisphere and Rankin grade

Myocardial infarction*

Yes

No

If yes: give details

Loss of vision*

Yes

No

If yes: give details

Damage to major artery*

Yes

No

If yes:

Common femoral

Superficial femoral

Damage to major vein*

Yes

No

If yes:

Common femoral

Popliteal

Damage to motor nerve*

Yes

No

If yes:

Femoral

Tibial

Popliteal

Other

Yes

No

If yes: give details

***If not previously reported as a Serious Adverse Event, details of these should be reported as a Serious Adverse Event.**

HOSPITAL ADMISSIONS

Has the participant been admitted to hospital for any reason since the initial procedure?

Yes No

If yes: give reason

Hospital admitted to

Date admitted

 / /

Date discharged

 / /

TREATMENT TO STUDY LEG OUTWITH THE CLASS TRIAL PROTOCOL

Has the participant had treatment to the study leg outwith the CLASS trial protocol since being recruited to CLASS?

Yes No

If yes, give date of treatment

 / /

details of treatment

TREATMENT TO CONTRALATERAL LEG

Has the participant had treatment to the contralateral leg since being recruited to CLASS?

Yes No

If yes, give date of treatment

 / /

details of treatment

Study Number

--	--	--	--	--	--

CLASS

Comparison of **LA**ser, **S**urgery and foam **S**clerotherapy

Confidential

Thank you for helping us with our research.
We would be very grateful if you could complete this
questionnaire.

SECTION A: DESCRIBING YOUR OWN HEALTH TODAY – (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today.

- | | | |
|---|--|--------------------------|
| A1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| A2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| A3. Usual Activities
<i>(e.g. work, study, housework, family or leisure activities)</i> | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| A4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| A5. Anxiety/Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

A6. Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box below to the point on the scale that best indicates how good or bad your health state is today.

Your
health
state
today

*Best imaginable
health state*

100

—
—
—

—
—
—
90

—
—
—

80

—
—
—

70

—
—
—

60

—
—
—

50

—
—
—

40

—
—
—

30

—
—
—

20

—
—
—

10

—
—
—

—
—
—
0

*Worst imaginable
health state*

SECTION B: YOUR GENERAL HEALTH (SF-36)

Please fill in all the questions by crossing the relevant box of the answer that applies to you.

These questions ask for your views about your health and how you feel about life in general. Do not spend too much time in answering as your immediate response is likely to be the most accurate, but please make sure you answer every question.

B1. In general, would you say your health is?

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities , such as running, lifting heavy objects, participating in strenuous sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Walking more than one mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Walking several hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Bathing and dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B8. During the past 4 weeks, how much did pain interfere with your normal work (including both outside the home and housework)?

Not at all

A little bit

Moderately

Quite a bit

Extremely

B9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

All of the time Most of the time Some of the time A little of the time None of the time

- | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) Did you feel full of life? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Have you been very nervous? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you felt so down in the dumps that nothing could cheer you up? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) Have you felt calm and peaceful? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) Have you felt downhearted and depressed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g) Did you feel worn out? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h) Have you been happy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i) Did you feel tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

B10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc)?

All of the time

Most of the time

Some of the time

A little of the time

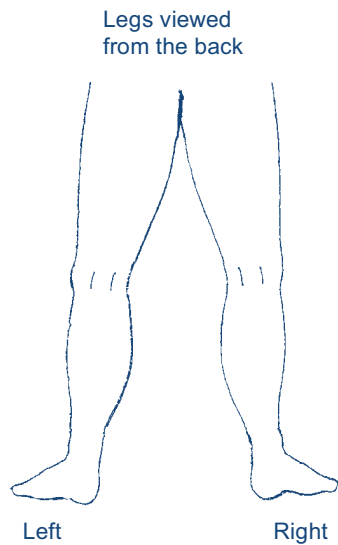
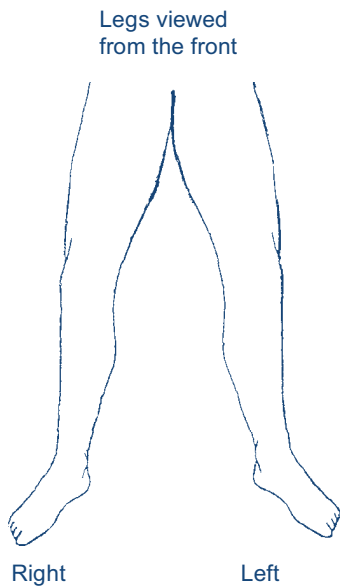
None of the time

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anyone I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION C: YOUR VARICOSE VEINS

C1. Please draw in your varicose veins in the diagram(s) below:



C2. In the last two weeks, for how many days did your varicose veins cause you pain or ache? (Please cross one box for each leg)

	Right Leg	Left Leg
None at all	<input type="checkbox"/>	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>	<input type="checkbox"/>

C3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins? (Please cross one box)

None at all	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>

C4. In the last two weeks, how much ankle swelling have you had? (Please cross one box)

None at all	<input type="checkbox"/>
Slight ankle swelling	<input type="checkbox"/>
Moderate ankle swelling (causing you to sit with your feet up whenever possible)	<input type="checkbox"/>
Severe ankle swelling (causing you difficulty putting on your shoes)	<input type="checkbox"/>

C5. In the last two weeks, have you worn support stockings or tights? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those I bought myself without a doctor's prescription	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear occasionally	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear every day	<input type="checkbox"/>	<input type="checkbox"/>

C6. In the last two weeks, have you had any itching in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only above the knee	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only below the knee	<input type="checkbox"/>	<input type="checkbox"/>
Both above and below the knee	<input type="checkbox"/>	<input type="checkbox"/>

C7. Do you have any purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C8. Do you have a rash or eczema in the area of your ankle? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but it does not require any treatment from a doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>
Yes, and it requires treatment from my doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>

C9. Do you have a skin ulcer associated with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C10. Does the appearance of your varicose veins cause you concern? (Please cross one box)

No	<input type="checkbox"/>
Yes, their appearance causes me slight concern	<input type="checkbox"/>
Yes, their appearance causes me moderate concern	<input type="checkbox"/>
Yes, their appearance causes me a great deal of concern	<input type="checkbox"/>

C11. Does the appearance of your varicose veins influence your choice of clothing including tights? (Please cross one box)

No	<input type="checkbox"/>
Occasionally	<input type="checkbox"/>
Often	<input type="checkbox"/>
Always	<input type="checkbox"/>

C12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities? (Please cross one box)

No

I have been able to work but my work
has suffered to a slight extent

I have been able to work but my work
has suffered to a moderate extent

My veins have prevented me from
working one day or more

C13. During the last two weeks have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)? (Please cross one box)

No

Yes, my enjoyment has suffered
to a slight extent

Yes, my enjoyment has suffered
to a moderate extent

Yes, my veins have prevented me
taking part in any leisure activities

SECTION D: YOUR RECOVERY

In this section we are interested in your activities during your recovery from your treatment for varicose veins. This includes questions on:

- for how long you wore your support stocking(s)
- how soon after your treatment you were able to do certain activities without discomfort
- whether you did anything yourself to try and help your recovery.

It may be hard for you to remember the answers to some of these questions, but it would be really helpful if you could be as accurate as you can be from your memory.

First of all, we are interested in *how long* you wore your support stocking(s).

EXAMPLE OF HOW TO COMPLETE THIS QUESTION

If you wore your stocking(s) all the time (day and night, i.e. 24 hours) for 5 days, then, during the day only for a further 3 weeks, you would complete the question as follows:

I wore my support stocking(s):

Not at all

Day and night (i.e. 24 hours) for

days, then during the day only for

days

Other (please explain)

PLEASE NOW COMPLETE THIS BOX TO TELL US HOW LONG YOU WORE YOUR SUPPORT STOCKING(S)

PLEASE CROSS THE RELEVANT BOX AND COMPLETE THE SENTENCE

I wore my support stocking(s):

Not at all

Day and night (i.e. 24 hours) for

days, then during the day only for

days

Other (please explain)

For each of the following activities we are interested in:

- whether you do not normally do this activity; or
- whether you normally do this activity but have not yet done so since your treatment; or
- *how soon after your treatment for varicose veins you carried out this activity.*

EXAMPLES OF HOW TO COMPLETE THESE QUESTIONS

If you first had a bath or shower 6 days after treatment, you would answer as follows:

Having a bath or shower:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

If you never drive a car, you would cross the box as follows:

Driving a car:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

THE FOLLOWING QUESTIONS ARE FOR YOU TO ANSWER

1. Bending the leg(s) (without discomfort):

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

2. Lifting heavy objects (without discomfort):

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

3. Moving from a standing to a sitting position (without discomfort):

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

4. Standing still for a long time i.e. more than 15 minutes (without discomfort):

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

5. Walking short distances i.e. less than 20 minutes (without discomfort):

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

6. Walking long distances i.e. more than 20 minutes:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

7. Having a bath or shower:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

8. Driving a car:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

9. Doing housework:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

10. Looking after children:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

11. Wearing clothes that show the legs:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

12. Partial return to normal work/employment:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

13. Full return to normal work/employment:

I don't normally do this

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

14. Going out socially (such as going to the cinema, theatre, a restaurant etc.):

Please describe a social activity that is important to you:

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

15. Sporting activity or exercise (such as swimming, going to the gym, cycling, running, jogging, horse-riding, hill-walking, golf etc.):

Please describe a sporting activity that is important to you:

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my treatment

OR

days after my treatment

OR

weeks after my treatment

16. Anything else that you do that is important to you, not already mentioned:

Please describe the activity:

I normally do this, but haven't done so since my treatment

I have done this since my treatment. I did it for the first time:

on the day of my
treatment

OR

days after my
treatment

OR

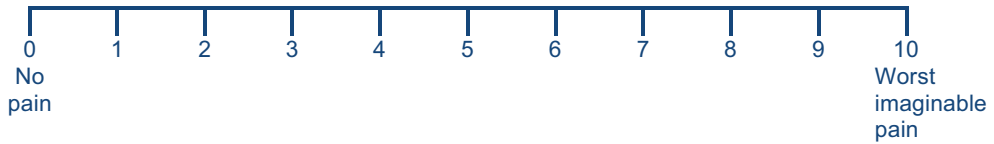
weeks after my
treatment

Finally, was there anything that you did in order to help your recovery from your treatment for varicose veins? For example, keeping your leg raised while sitting. Please complete the following sentence:

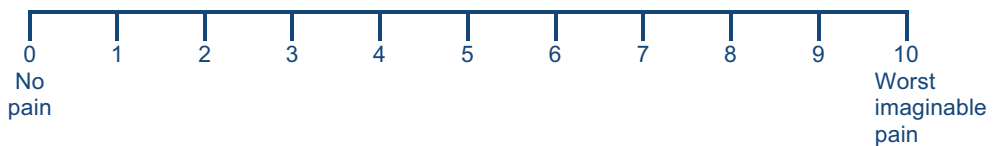
To help my recovery I _____

SECTION E: PAIN

- E1. Please rate the worst pain that you experienced while you were having your treatment for varicose veins.** The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a cross (X) on the line that best indicates the rating of the pain you experienced while you were having your treatment for varicose veins.



- E2. Please rate the worst pain that you have experienced while recovering in the days and weeks after your treatment for varicose veins.** The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a cross (X) on the line that best indicates the rating of the pain you experienced while recovering from your treatment for varicose veins.



THANK YOU

Thank you very much for your time and patience in filling in this questionnaire. Please hand the questionnaire back to the research nurse or return it in the enclosed reply-paid envelope to the Trial Office in Aberdeen.

The information you have given us will be extremely useful in helping us carry out research. It will be treated with the strictest confidence and kept securely.

Thank you again for your help

If you would like any further information or have any queries about the study, please contact:

The CLASS Trial Office in Aberdeen (Tel: 01224 XXXXXX)

This study is taking place across the UK but the questionnaires are being processed in Aberdeen at The Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.

Reminder letter to participants who do not return 6 week or 6 month questionnaire

Date

<<Title>> <<Name>> << Surname>>

Study No.

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>«Address3»

<<Postcode>>«Address4»

Dear <<Title>> <<Surname>>

Title of Study:

Thank you very much for taking part in the CLASS Study.

When you attended your follow-up appointment recently, we gave you a questionnaire to take home and complete. Unfortunately we have not yet received it back from you (if it is in the post, sorry to bother you and please ignore this reminder).

We are keen to find out how you have been getting on since your varicose veins were treated. It is very important for the success of the study that we have as much information as possible about you.

Some of the questions may not seem relevant but we would be very grateful if you could try to fill them all in. If you have any problems in completing the questionnaires, a friend or relative may be able to help you. Alternatively, please contact the CLASS Study Office; we will be happy to help in any way we can.

Please return the questionnaire in the reply-paid envelope provided.

In the meantime, if you require any further help or information about the Study, please contact the Study office.

Yours sincerely

Cover letter to send with six-week questionnaire for patients who fail to attend for the six-week follow-up appointment

Date

<<Title>> <<Name>> << Surname>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>«Address3»
<<Postcode>>«Address4»

Study No.

Dear <<Title>> <<Surname>>

Thank you very much for taking part in the CLASS Study.

We are sorry that you have been unable to attend a six-week follow-up appointment.

We are keen to find out how you have been getting on since your varicose veins were treated. It is very important for the success of the study that we have as much information as possible about you.

Some of the questions may not seem relevant but we would be very grateful if you could try to fill them all in. If you have any problems in completing the questionnaires, a friend or relative may be able to help you. Alternatively, please contact the CLASS Study Office; we will be happy to help in any way we can.

Please return the questionnaire in the reply-paid envelope provided.

In the meantime, if you require any further help or information about the Study, please contact the Study office. Likewise, if you would like to re-arrange a six-week follow-up appointment with the research nurse, please do contact on

Yours sincerely

Reminder letter for the six-week or six month questionnaire for patients who fail to attend for the follow-up appointment

Date

<<Title>> <<Name>> << Surname>>

Study No.

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>«Address3»

<<Postcode>>«Address4»

Dear <<Title>> <<Surname>>

Thank you very much for taking part in the CLASS Study.

Recently, we sent you a questionnaire to complete. Unfortunately we have not yet received it back from you (if it is in the post, sorry to bother you and please ignore this reminder).

We are keen to find out how you have been getting on since your varicose veins were treated. It is very important for the success of the study that we have as much information as possible about you.

Some of the questions may not seem relevant but we would be very grateful if you could try to fill them all in. If you have any problems in completing the questionnaires, a friend or relative may be able to help you. Alternatively, please contact the CLASS Study Office; we will be happy to help in any way we can.

Please return the questionnaire in the reply-paid envelope provided.

In the meantime, if you require any further help or information about the Study, please contact the Study office.

Yours sincerely



Comparison of LAser, Surgery
and foam Sclerotherapy

6 MONTH ASSESSMENT

Study Number

--	--	--	--	--	--

STUDY LEG

Right

Left

Date of 6 month assessment

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

DUPLEX SCAN Complete for study leg only

	Not examined	Complete occlusion (absent)	Partial occlusion	No occlusion (patent)	If patent, is reflux	
					Present	Absent
Groin - long saphenous (flush with CFV – i.e within 1cm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Groin - long saphenous (within 3cm of CFV)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Common femoral/superficial vein*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid thigh - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below knee - long saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short saphenous (flush with popliteal - i.e. within 1cm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short saphenous (within 3cm of popliteal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Popliteal vein*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mid calf - short saphenous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Occlusion in the common femoral vein or popliteal fossa-popliteal vein (DVT) should be reported as a Serious Adverse Event (if not already reported)

Name of person performing duplex scan

--

Date of duplex scan

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

CEAP CLASSIFICATION

Complete for study leg only - Please tick appropriate response

- C0 No visible or palpable signs of venous disease.
- C1 Telangiectasis or reticular veins. Veins less than 3 mm
- C2 Varicose veins. Veins over 3 mm
- C3 Edema
- C4 Skin and subcutaneous changes
- C4a Pigmentation or eczema
- C4b Lipodermatosclerosis or atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer

VENOUS CLINICAL SEVERITY SCORE (VCSS)

Complete for study leg only

PAIN

- | | | | |
|-------------------------------|---|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Occasional, not restricting activity or requiring analgesics | <input type="checkbox"/> Daily, moderate activity limitation, occasional analgesics | <input type="checkbox"/> Daily, severe limiting activities or requiring regular use of analgesics |
|-------------------------------|---|---|---|

VARICOSE VEINS i.e. >3mm

- | | | | |
|-------------------------------|---|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Few, scattered branch varicose veins | <input type="checkbox"/> Multiple: GSV varicose veins confined to calf or thigh | <input type="checkbox"/> Extensive: thigh and calf or GSV and SSV distribution |
|-------------------------------|---|---|--|

VENOUS EDEMA

- | | | | |
|-------------------------------|---|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Evening ankle only | <input type="checkbox"/> Afternoon edema, above ankle | <input type="checkbox"/> Morning edema above ankle and requiring activity change, elevation |
|-------------------------------|---|---|---|

SKIN PIGMENTATION

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> None or focal, low intensity (tan) | <input type="checkbox"/> Diffuse, but limited in area and old (brown) | <input type="checkbox"/> Diffuse over most of gaiter area (lower 1/3) or recent pigmentation (purple) | <input type="checkbox"/> Wider distribution (above lower 1/3), recent pigmentation |
|---|---|---|--|

INFLAMMATION

- | | | | |
|-------------------------------|---|--|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Mild cellulitis, limited to marginal area around ulcer | <input type="checkbox"/> Moderate cellulitis, involves most of gaiter area (lower 2/3) | <input type="checkbox"/> Severe cellulitis (lower 1/3 and above) or significant venous eczema |
|-------------------------------|---|--|---|

INDURATION

- | | | | |
|-------------------------------|--|--|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Focal, circum-malleolar (<5 cm) | <input type="checkbox"/> Medial or lateral, less than lower 1/3 of leg | <input type="checkbox"/> Entire lower 1/3 of leg or more |
|-------------------------------|--|--|--|

ACTIVE ULCERS, N

- | | | | |
|----------------------------|----------------------------|----------------------------|-----------------------------|
| <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> >2 |
|----------------------------|----------------------------|----------------------------|-----------------------------|

ACTIVE ULCERATION DURATION

- | | | | |
|-------------------------------|------------------------------------|--|---|
| <input type="checkbox"/> None | <input type="checkbox"/> <3 months | <input type="checkbox"/> >3 months, <1year | <input type="checkbox"/> Not healed >1 year |
|-------------------------------|------------------------------------|--|---|

ACTIVE ULCER, SIZE

- | | | | |
|-------------------------------|---|--|---|
| <input type="checkbox"/> None | <input type="checkbox"/> <2 cm diameter | <input type="checkbox"/> 2-6 cm diameter | <input type="checkbox"/> >6 cm diameter |
|-------------------------------|---|--|---|

COMPRESSIVE THERAPY

- | | | | |
|--|--|--|---|
| <input type="checkbox"/> Not used or not compliant | <input type="checkbox"/> Intermittent use of stockings | <input type="checkbox"/> Wears elastic stockings most days | <input type="checkbox"/> Full compliance: stockings + elevation |
|--|--|--|---|

COMPLICATIONS

Numbness

Yes

No

If yes: state distribution/dimensions

Persistent tenderness/discomfort

Yes

No

If yes: state distribution/dimensions

Skin loss/ulceration

Yes

No

If yes: state distribution/dimensions

Lumpiness

Yes

No

If yes: state distribution/dimensions

Development of thread vein

Yes

No

If yes: state distribution/dimensions

Skin staining

Yes

No

If yes: state distribution/dimensions

Deep vein thrombosis*

Yes

No

If yes: state distribution/dimensions

Pulmonary embolus*

Yes

No

If yes: give details of severity

Other

Yes

No

If yes, give details

***If not already reported as a serious adverse event, details of these should be reported as a serious adverse event**

HOSPITAL ADMISSIONS

Has the participant been admitted to hospital for any reason since the six week assessment? Yes No

Yes

No

If yes, give reason

Hospital admitted to

Date admitted

 / /

Date discharged

 / /

TREATMENT TO STUDY LEG OUTWITH THE CLASS TRIAL PROTOCOL

Has the participant had treatment to the study leg outwith the CLASS trial protocol since being recruited to CLASS? Yes No

Yes

No

If yes, give date of treatment

 / /

details of treatment

TREATMENT TO CONTRALATERAL LEG

Has the participant had treatment to the contralateral leg since being recruited to CLASS? Yes No

Yes

No

If yes, give date of treatment

 / /

details of treatment

DUPLEX SCANS TO STUDY LEG

Apart from the scans undertaken at recruitment and at six week and six month follow-up, has the participant had any **additional scans** to the study leg since being recruited to CLASS? Yes No

Yes

No

*If yes, give number of **additional** scans*

Study Number

--	--	--	--	--	--

CLASS

Comparison of **LA**ser, **S**urgery and foam **S**clerotherapy

CONFIDENTIAL

Thank you for helping us with our research.
We would be very grateful if you could complete this
questionnaire.

SECTION A: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

- | | | |
|---|--|--------------------------|
| A1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| A2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| A3. Usual Activities
<i>(e.g. work, study, housework, family or leisure activities)</i> | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| A4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| A5. Anxiety/Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

A6. Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box below to the point on the scale that best indicates how good or bad your health state is today.

Your
health
state
today

*Best imaginable
health state*

100

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

—

90

80

70

60

50

40

30

20

10

0

*Worst imaginable
health state*

SECTION B: YOUR GENERAL HEALTH (SF-36)

Please fill in all the questions by crossing the relevant box of the answer that applies to you. These questions ask for your views about your health and how you feel about life in general. Do not spend too much time in answering as your immediate response is likely to be the most accurate, but please make sure you answer every question.

B1. In general, would you say your health is?

Excellent

Very good

Good

Fair

Poor

B2. Compared to one year ago, how would you rate your health in general now?

Much better
now than one
year ago

Somewhat better
now than one
year ago

About the
same as
one year ago

Somewhat worse
now than one
year ago

Much worse
now than one
year ago

B3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities , such as running, lifting heavy objects, participating in strenuous sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Walking more than one mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Walking several hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Bathing and dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Were limited in the kind of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Had difficulty performing the work or other activities (for example it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other daily regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Did work or other activities less carefully than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B8. During the past 4 weeks, how much did pain interfere with your normal work (including both outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Did you feel full of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Have you been very nervous?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Have you felt downhearted and depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Did you feel worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Have you been happy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc)?

All of the time

Most of the time

Some of the time

A little of the time

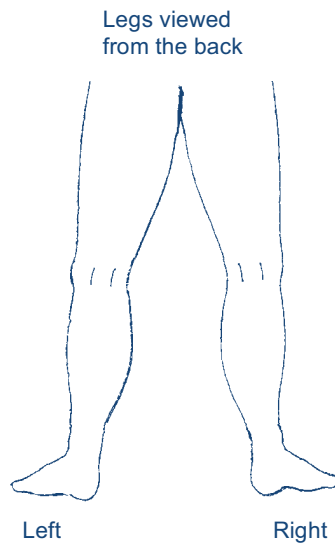
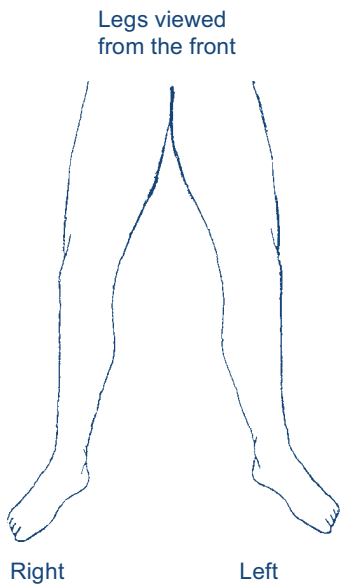
None of the time

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anyone I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION C: YOUR VARICOSE VEINS

C1. Please draw in your varicose veins in the diagram(s) below:-



C2. In the last two weeks, for how many days did your varicose veins cause you pain or ache? (Please cross one box for each leg)

	Right Leg	Left Leg
None at all	<input type="checkbox"/>	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>	<input type="checkbox"/>

C3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins? (Please cross one box)

None at all	<input type="checkbox"/>
Between 1 and 5 days	<input type="checkbox"/>
Between 6 and 10 days	<input type="checkbox"/>
For more than 10 days	<input type="checkbox"/>

C4. In the last two weeks, how much ankle swelling have you had? (Please cross one box)

None at all	<input type="checkbox"/>
Slight ankle swelling	<input type="checkbox"/>
Moderate ankle swelling (causing you to sit with your feet up whenever possible)	<input type="checkbox"/>
Severe ankle swelling (causing you difficulty putting on your shoes)	<input type="checkbox"/>

C5. In the last two weeks, have you worn support stockings or tights? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those I bought myself without a doctor's prescription	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear occasionally	<input type="checkbox"/>	<input type="checkbox"/>
Yes, those my doctor prescribed for me which I wear every day	<input type="checkbox"/>	<input type="checkbox"/>

C6. In the last two weeks, have you had any itching in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only above the knee	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but only below the knee	<input type="checkbox"/>	<input type="checkbox"/>
Both above and below the knee	<input type="checkbox"/>	<input type="checkbox"/>

C7. Do you have any purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C8. Do you have a rash or eczema in the area of your ankle? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes, but it does not require any treatment from a doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>
Yes, and it requires treatment from my doctor or district nurse	<input type="checkbox"/>	<input type="checkbox"/>

C9. Do you have a skin ulcer associated with your varicose veins? (Please cross one box for each leg)

	Right Leg	Left Leg
No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	<input type="checkbox"/>	<input type="checkbox"/>

C10. Does the appearance of your varicose veins cause you concern? (Please cross one box)

No	<input type="checkbox"/>
Yes, their appearance causes me slight concern	<input type="checkbox"/>
Yes, their appearance causes me moderate concern	<input type="checkbox"/>
Yes, their appearance causes me a great deal of concern	<input type="checkbox"/>

C11. Does the appearance of your varicose veins influence your choice of clothing including tights? (Please cross one box)

- No
- Occasionally
- Often
- Always

C12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities? (Please cross one box)

- No
- I have been able to work but my work has suffered to a slight extent
- I have been able to work but my work has suffered to a moderate extent
- My veins have prevented me from working one day or more

C13. During the last two weeks have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)? (Please cross one box)

- No
- Yes, my enjoyment has suffered to a slight extent
- Yes, my enjoyment has suffered to a moderate extent
- Yes, my veins have prevented me taking part in any leisure activities

SECTION D: YOUR SYMPTOMS

Listed below are a number of symptoms that you may or may not have experienced since you developed varicose veins.

Please indicate by crossing **Yes** or **No** whether you have experienced any of these symptoms since you developed varicose veins, and whether you believe that these symptoms are related to your varicose veins.

	I have experienced this symptom since I developed varicose veins		This symptom is related to my varicose veins	
D1. Pain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D2. Hardening of the skin on the legs	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D3. Redness of the skin on the legs	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D4. Sleep difficulties	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D5. Swelling of the ankle	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D6. Discolouration or brown staining on the leg	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D7. Stiff joints	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D8. Weight loss	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D9. Dizziness	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D10. Fatigue	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D11. Breaks in the skin or ulcers on the leg	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D12. Sore eyes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D13. Breathlessness	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
D14. Loss of strength	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

SECTION E: YOUR VIEWS ABOUT YOUR VARICOSE VEINS

We are interested in your own personal views of how you now see your varicose veins. Please indicate how much you agree or disagree with the following statements about your varicose veins by crossing the appropriate box.

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E1. My varicose veins will last a short time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E2. My varicose veins are likely to be permanent rather than temporary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E3. My varicose veins will last for a long time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E4. These varicose veins will pass quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E5. I expect to have these varicose veins for the rest of my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E6. My varicose veins are a serious condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E7. My varicose veins have major consequences on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E8. My varicose veins do not have much effect on my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E9. My varicose veins strongly affect the way others see me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E10. My varicose veins have serious financial consequences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E11. My varicose veins cause difficulties for those who are close to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E12. There is a lot which I can do to control my symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E13. What I do can determine whether my varicose veins get better or worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E14. The course of my varicose veins depends on me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E15. Nothing I do will affect my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E16. I have the power to influence my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E17. My actions will have no effect on the outcome of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E18. My varicose veins will improve in time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E19. There is very little that can be done to improve my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E20. My treatment will be effective in curing my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E21. The negative effects of my varicose veins can be prevented (avoided) by my treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E22. My treatment can control my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E23. There is nothing which can help my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E24. The symptoms of my varicose veins are puzzling to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E25. My varicose veins are a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Views about your varicose veins	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
E26. I don't understand my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E27. My varicose veins don't make any sense to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E28. I have a clear picture or understanding of my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E29. The symptoms of my varicose veins change a great deal from day to day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E30. My symptoms come and go in cycles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E31. My varicose veins are very unpredictable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E32. I go through cycles in which my varicose veins get better and worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E33. I get depressed when I think about my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E34. When I think about my varicose veins I get upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E35. My varicose veins make me feel angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E36. My varicose veins do not worry me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E37. Having these varicose veins makes me feel anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E38. My varicose veins make me feel afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION F: CAUSES OF YOUR VARICOSE VEINS

We are interested in what you consider may have been the cause of your varicose veins. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your varicose veins rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your varicose veins. Please indicate how much you agree or disagree that they were causes for you by crossing the appropriate box.

Possible causes	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
F1. Stress or worry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F2. Hereditary - it runs in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F3. A germ or virus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F4. Diet or eating habits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F5. Chance or bad luck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F6. Poor medical care in my past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F7. Pollution in the environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F8. My own behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F9. My mental attitude, e.g. thinking about life negatively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F10. Family problems or worries caused my varicose veins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F11. Overwork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F12. My emotional state, e.g. feeling down, lonely, anxious, empty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F13. Ageing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F14. Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F15. Smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F16. Accident or injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F17. My personality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F18. Altered immunity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the table below, please list in rank-order the three most important factors that you now believe caused your illness. You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me:-

1. _____

2. _____

3. _____

SECTION G: YOUR MOST RECENT ADMISSION TO HOSPITAL

This section of the questionnaire will help us to find out how much it costs you to use health services. We will ask about your most recent admission to hospital, your most recent outpatient appointment and your most recent appointment with a GP. We wish to know how much money and time were spent by you and any companion in attending these appointments and as a result of any hospital admission you may have had.

If, in the last 6 months, you were **not** admitted to hospital please go to **Section H**.

G1. Please cross the box that best describes how you travelled. If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey.

- | | | | |
|-------------|--------------------------|------------------------------|--------------------------|
| Bus | <input type="checkbox"/> | Hospital car | <input type="checkbox"/> |
| Train | <input type="checkbox"/> | Ambulance | <input type="checkbox"/> |
| Taxi | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
| Private car | <input type="checkbox"/> | | |
-

G2. If you travelled by bus, train or taxi to hospital what was the total cost of the (one-way) journey? Please write the cost in the box below. Please put zero if you did not travel by bus, train or taxi at all or if you did not pay a fare.

Cost of (one-way) fare (£) - pence

G3. If you travelled by private car about how many miles did you travel one-way? Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way

G4. If you travelled by private car and you or your companion had to pay a parking fee how much did this cost? Please write the cost in the box below. Please put zero if you did not pay a parking fee.

Expenditure on parking fee (£) - pence

G5. When you were admitted to the hospital, how long did you spend there? Please write the number of days in the box below.

Number of days

G6. What would you otherwise have been doing as your main activity if you had not had to be admitted to hospital? Please cross the box that best applies to you.

- | | | | |
|---------------------------------|--------------------------|------------------------------|--------------------------|
| Paid work | <input type="checkbox"/> | Unemployed | <input type="checkbox"/> |
| Housework | <input type="checkbox"/> | Voluntary work | <input type="checkbox"/> |
| Childcare | <input type="checkbox"/> | Leisure activities | <input type="checkbox"/> |
| Caring for a relative or friend | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
-

G7. When you were admitted to hospital, did anyone come with you?

Yes Go to **G8**

No Go to **Section H**

G8. Who accompanied you to the hospital? Please cross the box that best describes the main person who accompanied you to the hospital.

Partner/spouse

Paid caregiver

Other relative

Other (please specify below)

Friend

G9. Please cross the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you to the hospital.

Paid work

Unemployed

Housework

Voluntary work

Childcare

Leisure activities

Caring for a relative or friend

Other (please specify below)

G10. Did your main companion take time off from paid work (or business activity if self-employed)?

Yes Go to **G11**

No Go to **Section H**

G11. Please write the number of hours your companion took off from paid work (or business activity if self-employed) in the box below. Please put zero if your main companion did not take time off from paid work (or business activity if self-employed) to accompany you to the hospital.

Number of hours

G12. Whilst you were in hospital, approximately how many times did your main companion come to visit you?

Number of times

SECTION H: YOUR MOST RECENT OUTPATIENT VISIT

If, in the last 6 months, you did **not** have an outpatient's appointment, please go to **Section I**.

H1. Please cross the box that best describes how you travelled. If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey.

Bus	<input type="checkbox"/>	Hospital car	<input type="checkbox"/>
Train	<input type="checkbox"/>	Ambulance	<input type="checkbox"/>
Taxi	<input type="checkbox"/>	Other (please specify below)	<input type="checkbox"/>
Private car	<input type="checkbox"/>		

H2. If you travelled by bus, taxi or train to hospital what was the total cost of the (one-way) journey? Please write the cost in the box below. Please put zero if you did not travel by bus, train or taxi at all or if you did not pay a fare.

Cost of (one-way) fare (£) - pence

H3. If you travelled by private car about how many miles did you travel one-way? Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way

H4. If you travelled by private car and you or your companion had to pay a parking fee how much did this cost? Please write the cost in the box below. Please put zero if you did not pay a parking fee.

Expenditure on parking fee (£) - pence

H5. When you visited outpatients, how long did it take to travel there? Please write the number of hours and minutes in the box below.

Number of hours - minutes

H6. When you visited outpatients, how long did you spend there? Please write the number hours and minutes in the box below.

Number of hours - minutes

H7. Please cross the box that best describes what you otherwise would have been doing as your main activity if you had not been visiting outpatients?

- | | | | |
|---------------------------------|--------------------------|------------------------------|--------------------------|
| Paid work | <input type="checkbox"/> | Unemployed | <input type="checkbox"/> |
| Housework | <input type="checkbox"/> | Voluntary work | <input type="checkbox"/> |
| Childcare | <input type="checkbox"/> | Leisure activities | <input type="checkbox"/> |
| Caring for a relative or friend | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
-

H8. When you visited outpatients did anyone come with you?

Yes Go to **H9**

No Go to **Section I**

H9. Please cross the box that best describes the main person who accompanied you to outpatients.

Partner/spouse

Paid caregiver

Other relative

Other (please specify below)

Friend

H10. If your main companion travelled with you by bus or train approximately how much did they pay (one-way) in fares? Please write the approximate cost in the box below. Please put zero if your main companion did not travel by bus or train at all.

Cost of (one-way) fare (£) - pence

H11. Please cross the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you to outpatients.

Paid work

Unemployed

Housework

Voluntary work

Childcare

Leisure activities

Caring for a relative or friend

Other (please specify below)

SECTION I: YOUR MOST RECENT GP APPOINTMENT

11. Please cross the box that best describes how you travelled to your most recent GP appointment. If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey.

Walked	<input type="checkbox"/>	Bus	<input type="checkbox"/>
Cycled	<input type="checkbox"/>	Taxi	<input type="checkbox"/>
Private car	<input type="checkbox"/>	Other (please specify below)	<input type="checkbox"/>

12. If you travelled by bus or taxi, what was the cost of the (one-way) fare? Please write the cost in the box below. Please put zero if you did not travel by bus or taxi or if you did not pay the fare.

Cost of (one-way) fare (£) - pence

13. If you travelled by private car about how many miles did you travel one-way? Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way

14. If you travelled by private car and you or a companion had to pay a parking fee how much did this cost? Please write the cost in the box below. Please put zero if you did not pay for parking.

Expenditure on parking fee (£) - pence

15. When you visited the GP, how long did it take to travel there? Please write the number of minutes in the box below.

Number of minutes

--	--	--

16. When you visited the GP, how long did you spend there? Please write the number minutes in the box below. Please include in your answer the time spent waiting and also the time spent with the doctors and nurses

Number of minutes

--	--	--

17. Please cross the box that best describes what you otherwise would have been doing as your main activity if you had not visited the GP.

- | | | | |
|---------------------------------|--------------------------|------------------------------|--------------------------|
| Paid work | <input type="checkbox"/> | Unemployed | <input type="checkbox"/> |
| Housework | <input type="checkbox"/> | Voluntary work | <input type="checkbox"/> |
| Childcare | <input type="checkbox"/> | Leisure activities | <input type="checkbox"/> |
| Caring for a relative or friend | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
-

18. When you visited the GP did anyone come with you?

Yes Go to **I9**

No Go to **Section J**

19. Please cross the box(es) that best describe the person(s) who accompanied you to the GP surgery.

- | | | | |
|----------------|--------------------------|------------------------------|--------------------------|
| Partner/spouse | <input type="checkbox"/> | Paid caregiver | <input type="checkbox"/> |
| Other relative | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
| Friend | <input type="checkbox"/> | | |
-

110. If your main companion travelled with you by bus how much approximately did they pay (one-way) in fares (if anything)? Please write the cost in the box below. Please put zero if your main companion did not travel by bus at all.

Cost of (one-way) fare (£) - pence

111. Please cross the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you to the GP's surgery.

- | | | | |
|---------------------------------|--------------------------|------------------------------|--------------------------|
| Paid work | <input type="checkbox"/> | Unemployed | <input type="checkbox"/> |
| Housework | <input type="checkbox"/> | Voluntary work | <input type="checkbox"/> |
| Childcare | <input type="checkbox"/> | Leisure activities | <input type="checkbox"/> |
| Caring for a relative or friend | <input type="checkbox"/> | Other (please specify below) | <input type="checkbox"/> |
-

SECTION J: HEALTH SERVICE UTILISATION QUESTIONNAIRE

Please try to complete all the questions. Most questions can be answered by putting numbers or a cross in the appropriate boxes. In a few questions you are asked to write some details. This set of questions is about any appointments you may have had with a general practice in the past 6 months.

J1. Have you been to see a GP because of your varicose veins during the last 6 months?

Yes

No

If **Yes**, please give details:

How many appointments did you attend with a GP because of your varicose veins?

--	--

How many times did a GP visit you at home because of your varicose veins?

--	--

How many times did you have a telephone conversation with a GP because of your varicose veins?

--	--

J2. Please make a list below of all the medication you currently take:

This set of questions is about any appointments you may have had with other health care workers in the past 6 months.

J3. During the last 6 months have you had an appointment with any of these care providers because of your varicose veins:

A District Nurse? Yes No

If **Yes**, how many appointments have you had?

--	--

A Practice Nurse? Yes No

If **Yes**, how many appointments have you had?

--	--

An NHS physiotherapist? Yes No

If **Yes**, how many appointments have you had?

--	--

An Occupational Therapist? Yes No

If **Yes**, how many appointments have you had?

--	--

Other? (*please specify below*) Yes No

How many appointments have you had?

--	--

How many appointments have you had?

--	--

This set of questions is about any private health care you may have had in the past 6 months

J4. During the last 6 months have you paid for any private health care for your **varicose veins**?

Yes

No

If **Yes**, what sort of care did you pay for?

If **Yes**, and you had appointments, how many appointments did you have?

--	--

If you wish to provide further information please do so in the box below.

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire. Please hand the questionnaire back to the nurse or return it in the enclosed reply-paid envelope to the Trial Office in Aberdeen.

The information you have given us will be extremely useful in helping us carry out research. It will be treated with the strictest confidence and kept securely.

Thank you again for your help

If you would like any further information or have any queries about the study,
please contact:

The CLASS Trial Office in Aberdeen (Tel: 01224 XXXXXX)

This study is taking place across the UK but the questionnaires are being processed in Aberdeen at
The Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit,
Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.



CASE NOTE DATA ABSTRACTION FORM: USE OF SERVICES

Comparison of LAser, Surgery
and foam Sclerotherapy

(Use of hospital services from discharge following index
admission until the end of the last day of follow-up)

Study Number

Date randomised

 / /

Last day of follow-up

 / /

1. Has the patient been admitted to hospital?

Yes

No

If Yes, please give details below

Specialty

Date admitted

Date discharged

e.g. general surgery	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

2. Has the patient had another operation?

Yes

No

If Yes, please give details below

Specialty	Date admitted			Date discharged																
e.g. general surgery	2	2	/	0	7	/	2	0	0	8	0	8	/	0	8	/	2	0	0	8
	D	D	/	M	M	/	Y	Y	Y	Y	D	D	/	M	M	/	Y	Y	Y	Y
	D	D	/	M	M	/	Y	Y	Y	Y	D	D	/	M	M	/	Y	Y	Y	Y
	D	D	/	M	M	/	Y	Y	Y	Y	D	D	/	M	M	/	Y	Y	Y	Y
	D	D	/	M	M	/	Y	Y	Y	Y	D	D	/	M	M	/	Y	Y	Y	Y
	D	D	/	M	M	/	Y	Y	Y	Y	D	D	/	M	M	/	Y	Y	Y	Y

3. Has the patient had any outpatient visits to the following specialties/departments?

Surgical

Yes

No

If Yes, how many visits?

Ear, Nose & Throat

Yes

No

If Yes, how many visits?

Medical

Yes

No

If Yes, how many visits?

Sexual Medicine/Urology

Yes

No

If Yes, how many visits?

Physiotherapy

Yes

No

If Yes, how many visits?

Occupational Therapy

Yes

No

If Yes, how many visits?

Dietician

Yes

If Yes, how many visits?

No

Pain Team

Yes

If Yes, how many visits?

No

Other?

Yes

If yes, please specify below

No

How many visits?

How many visits?



SERIOUS ADVERSE EVENT REPORT

Comparison of LAser, Surgery
and foam Sclerotherapy

To be completed for any serious adverse event, whether they are expected or unexpected, related or unrelated.

An event is deemed “serious” if the patient died; it involved or prolonged inpatient hospitalization; it involved persistent or significant disability or incapacity; was life threatening; or resulted in congenital anomaly or birth defect.

The events defined as expected are deep vein thrombosis, pulmonary embolism, anaphylactic shock, stroke, retinal arteriole occlusion, myocardial infarction, cutaneous necrosis and ulceration, epileptic fit, intra-arterial injection, injury to a major artery (common femoral or superficial femoral), injury to a major vein (common femoral or popliteal), injury to a motor nerve (femoral, tibial or peroneal), transient ischemic attack.

A. Patient Details

Hospital number

Study No.

Patient's initials

Date of birth

 / /

Age

Sex

Male

Female

Treating Hospital

B. Adverse Event

Place where adverse event took
place / detected

Date of event

 / /

Brief details of adverse event

Date of report

 / /

C. Cross all boxes appropriate to adverse event.

If any box is crossed the adverse event is serious

- Patient died
- Involved or prolonged inpatient hospitalisation
- Involved persistent or significant disability or incapacity
- Life threatening
- Congenital anomaly/birth defect
- An important medical event that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above

D. What treatment for varicose veins had the patient received?

Laser treatment Date(s) of procedure / /

Surgery Date(s) of procedure / /

Foam sclerotherapy

Date(s) and dose(s) of Fibrovein administered

	Concentration	Volume of foam	Batch number
1. <input type="text" value="DD"/> <input type="text" value="DD"/> / <input type="text" value="MM"/> <input type="text" value="MM"/> / <input type="text" value="YYYY"/> <input type="text" value="YY"/> <input type="text" value="YY"/> <input type="text" value="YY"/>	<input style="width: 50px;" type="text" value="%"/>	<input style="width: 50px;" type="text" value="ml"/>	<input style="width: 150px;" type="text"/>
2. <input type="text" value="DD"/> <input type="text" value="DD"/> / <input type="text" value="MM"/> <input type="text" value="MM"/> / <input type="text" value="YYYY"/> <input type="text" value="YY"/> <input type="text" value="YY"/> <input type="text" value="YY"/>	<input style="width: 50px;" type="text" value="%"/>	<input style="width: 50px;" type="text" value="ml"/>	<input style="width: 150px;" type="text"/>
3. <input type="text" value="DD"/> <input type="text" value="DD"/> / <input type="text" value="MM"/> <input type="text" value="MM"/> / <input type="text" value="YYYY"/> <input type="text" value="YY"/> <input type="text" value="YY"/> <input type="text" value="YY"/>	<input style="width: 50px;" type="text" value="%"/>	<input style="width: 50px;" type="text" value="ml"/>	<input style="width: 150px;" type="text"/>
4. <input type="text" value="DD"/> <input type="text" value="DD"/> / <input type="text" value="MM"/> <input type="text" value="MM"/> / <input type="text" value="YYYY"/> <input type="text" value="YY"/> <input type="text" value="YY"/> <input type="text" value="YY"/>	<input style="width: 50px;" type="text" value="%"/>	<input style="width: 50px;" type="text" value="ml"/>	<input style="width: 150px;" type="text"/>

Route of administration

Indication(s) for use

E. Was the adverse event 'expected'?

Is this serious adverse event one of:

- Deep vein thrombosis [*following foam, laser, surgery*]
- Pulmonary embolism [*following foam, laser, surgery*]
- Anaphylactic shock [*following foam*]
- Stroke [*following foam*]
- Retinal arterial occlusion [*following foam*]
- Myocardial infarction [*following foam*]
- Cutaneous necrosis and ulceration [*following foam*]
- Epileptic fit [*following foam*]
- Intra-arterial injection [*following foam*]
- Injury to a major artery (common femoral or superficial femoral) [*following surgery*]
- Injury to a major vein (common femoral or popliteal) [*following foam, laser, surgery*]
- Injury to a motor nerve (femoral, tibial or peroneal) [*following surgery*]
- Transient Ischemic Attack [*following foam*]

and therefore an “expected” serious adverse event?

Yes

No If NO, this could be a SUSAR

F. Concomitant drug(s) and history

Concomitant drug(s) and dates of administration (exclude those used to treat reaction)

Other relevant history (e.g. diagnostics, allergies etc)

G. Assessment of whether event was caused by study intervention

Is it reasonably likely that adverse event was caused by the study intervention?

Yes No

Why?

Name and position of person making this judgement

Date of assessment

 / /

Any subsequent information

H. Contact details for person initially reporting adverse event

Name

Address

Telephone

Email

I. Manufacturing and packaging information for fibrovein

Complete only if patient received foam sclerotherapy

Name and address of manufacturer

CP Pharmaceuticals Ltd
Wrexham Industrial Estate, Wrexham, Clwyd, LL13
9UF

Date report sent to manufacturer

 / /