UK Rotator Cuff Surgery Trial

UKCUFF

PATIENT INFORMATION SHEET

This study is about the clinical and cost effectiveness of surgical (arthroscopic or open) repairs for management of the rotator cuff tears. (10/H0402/24)

We are inviting you to take part in a research study. Before you decide whether to participate or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to decide whether or not you wish to be involved.

1. What is the purpose of this study?

The rotator cuff is a group of muscles that control movements within the shoulder. Tears of the rotator cuff are one of the most common causes of shoulder pain and dysfunction. Many patients require surgery to repair the tear, as non-surgical treatment like physiotherapy may not have helped restore shoulder function satisfactorily. Operations to repair the tendon can be done via an:

- Arthroscopic technique – where the tear is repaired through key-hole surgery, or a
- Mini-open/Open technique – where a longer skin incision is made to complete the repair procedure.

This study was designed to assess the best surgical technique for rotator cuff tears both in terms of recovery for patients and the costs involved.

2. Why have I been chosen?

You have been chosen because you are 50 years of age or older and have been diagnosed with a rotator cuff tear, deemed suitable for surgical repair.

3. Do I have to take part?

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason.

4. What will happen if I take part?

Sometimes we don't know which way of treating patients is best. To find out, we need to make comparisons between different treatments. To do this we will randomly allocate you to one of the following surgical options:

1. Arthroscopic Surgical Repair
2. Mini-open/Open Surgical Repair

Your surgeon routinely performs both these operations. Whichever one you are allocated to will be performed in the usual way by your surgeon. The benefits and problems associated with each treatment will be compared. This is called a randomised study.

5. What do I have to do?

If you agree to participate in the UKUFF trial, we may ask you for a blood sample. We hope to identify genes responsible for tears of the rotator cuff. We will provide you with the blood sample tubes and ask you take the equipment with you to your outpatients or pre-admission clinic appointment and ask to have the samples taken there. Due to the genetic nature of the blood analysis, only patients who identify as White British will be asked to give a blood sample.

You will also be asked to give a tissue sample. The tissue sample will be taken during your operation and is a very small amount which is routinely excised during rotator cuff repairs. The samples will be used to examine the condition of the tendon.

Involvement in the UKUFF trial will include completing questionnaires. These are specialised questionnaires, recognised as a means of assessing shoulder pain and function, and they also cover other health related questions. These will all be sent to you in the post with a free post envelope for them to be returned to our data centre. Follow up questionnaires will occur as follows:

- **At two and eight weeks** after the completion of the Rest then Exercise Programme/or two and eight weeks after your surgery, a member of the research team will ask you questions over the telephone.
- **8 months, 12 months and 24 months** after you first agreed to participate in the study a questionnaire will be sent to you in the post
- **12 months after your operation** you will be asked to undergo an MRI scan. The MRI scan is a detailed method of assessing the clinical and physical result of the operation.

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A diagram illustrating your involvement in the study is attached at the end of this information sheet.

6. Expenses and payments
If you are asked to attend an MRI scan 12 months after your operation, the costs incurred during this extra appointment will be reimbursed on request.

7. What are the possible benefits of taking part?
Your rotator cuff tear will be treated by experienced surgeons using widely recognised treatments. The information we get from this study will help improve the future treatment of people with rotator cuff tears.

8. What are the possible risks of taking part?
MRI is a safe and non-invasive technique, which does not involve ionising radiation. An MRI safety questionnaire will be asked at the time of arranging the scan appointment to help identify and minimise any possible risks.

9. Will my taking part be kept confidential?
All patient information is stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with you will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

10. What if I change my mind about taking part?
If you decide to withdraw from the study, your standard of care will not be affected. You will **still** be asked to attend the usual follow-up clinics required by your surgeon and hospital. These will not be part of the study.

11. What if there is a problem?
Complaints If you wish to complain formally, you can do this through the NHS Complaints Procedure, (details can be obtained from your hospital) or you can find further information on ethics in research on the National Research Ethics Service website (www.nres.npsa.nhs.uk).

Harm If you are harmed and this is due to someone's negligence then you may have grounds for legal action or compensation against the University of Oxford (in respect of any harm arising out of the participation in the Clinical Trial) or the NHS (in respect of any harm which has resulted from the clinical procedure being undertaken).

12. Will my GP be informed of my involvement in the study?
With your consent your GP will be notified of your participation in the UKUFF study.

13. What will happen to any samples I give?
The tissue and blood samples collected for the UKUFF trial will be sent to the Nuffield Department of Orthopaedic Surgery, in Oxford, for analysis.

14. How will the information I provide be used?
We plan to publish the results in a health journal so others can read about and learn from the results of the study.

15. Who is organising and funding the research?
This nationwide trial is being funded through the Heath Technology Assessment (HTA) Programme, which is part of the Department of Health. You can access information about them on the HTA website (www.hta.nhs.uk).

The Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal Sciences (www.ndorms.ox.ac.uk) a department of the University of Oxford, in Oxford will undertake the day to day running of the trial, under the supervision of Professor Andrew Carr. The University of Oxford will act as a sponsor for the study and will be responsible for the governance of the trial.

The Centre for Healthcare and Randomised Trials (CHaRT), Health Services Research Unit in the University of Aberdeen (www.charttrials.abdn.ac.uk) in Aberdeen will be responsible for collecting and monitoring the information generated.

16. Who has reviewed this study?

A Research Ethics Committee, the UK Comprehensive Research Network, each hospital's Research and Development Committee/Department and your local Orthopaedic Consultant have reviewed this study.

17. Further Information

If you require more information about this study please call one of the telephone numbers provided to speak to a clinical member of the research team or, alternatively look at the study website www.charttrials.abdn.ac.uk/ukuff.

Thank you for reading this.
If you have any questions or would like any more information please contact the UKUFF Study Office by phone:
XXXXX
Or email XXXXX

Please keep this information sheet for your records.

If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you.