

DSCI: Dichotomous Outcomes Form for Cross-Over Studies

PLEASE READ BEFORE STARTING:

- *N(included)* refers to either the number of participants included in a group of a controlled-clinical trial (CCT) or the number of participants randomized in a group in a randomized-controlled trial (RCT).

-Please do not indicate any units (including percentage signs) in the table cells. Numbers may be inputted to 2 decimal places, if that is the precision level reported in a study.

RefID: _____

1. Select the outcome:

Complete a separate form for each relevant outcome reported in the study.

- Abdominal aortic aneurysm
- Activated partial thromboplastin time (aPTT) (above/below threshold). Indicate threshold. _____
- Acute coronary syndrome
- Adherence to prescribed cardiovascular drug regimen
- Adverse Event Other (other than neurologic, allergic, gastrointestinal, bleeding, withdrawal due to adverse event). Please specify. _____
- Alanine transaminase (ALT) (Raised)
- Allergic reactions (All types)
- Amputation
- Anaphylaxis/allergic shock
- Anemia
- Ankle-brachial index (above/below threshold). Indicate threshold.
- Arrhythmia (All types)
- Aspartate aminotransferase (AST) (Raised)
- Asthma
- Atrial fibrillation
- Bleeding time (above/below threshold). Indicate threshold.
- Blood urea nitrogen (BUN) (Raised)
- Carotid artery disease (not measured by IMT or Doppler). Please specify. _____
- Carotid dilation/stenting
- Carotid intima-media thickness (IMT), as measured by Doppler ultrasound (above/below threshold). Indicate threshold. _____
- Claudication (pain walking)
- Clotting time (above/below threshold). Indicate threshold.

- Composite cardiovascular outcome (e.g. MI + Stroke + Vascular Death). Please specify.

- Congestive heart/cardiac failure
- Constipation
- Coronary artery bypass graft (CABG)
- Coronary/cerebral arterial calcification score (above/below threshold). Indicate threshold.

- C-reactive protein (above/below threshold). Indicate threshold.

- Creatinine (Raised)
- Diarrhea
- Ejection fraction (above/below threshold). Indicate threshold.

- Electrocardiographic (ECG) measurements or 24 hr ambulatory ECG/Holter monitoring. Please specify outcome.

- Fasting blood glucose (above/below threshold). Indicate threshold.

- Flatulence
- Gastrointestinal (GI) adverse events (All types)
- Gastrointestinal bleed (All types)
- Gastrointestinal bleed (Lower)
- Gastrointestinal bleed (Upper)
- Glycosylated hemoglobin (above/below threshold). Indicate threshold.
- Heart block
- Heartburn
- Hematologic abnormality. Please specify outcome.

- Hematuria
- Hemorrhagic stroke
- High-density lipoprotein cholesterol (HDL-C) (above/below threshold). Indicate threshold.

- Hospitalization
- Hospitalization (Prolonged)
- Hypertension (HTN), new or worsening (e.g. need for change in therapy)
- Hypotension
- Internal bleed (All types)
- International normalized ratio (INR) (above/below threshold). Indicate threshold.
- Intracerebral bleed
- Intracranial bleed
- Intraventricular bleed
- Leukopenia

- Limb thrombosis/Leg ischemia
- Lipoprotein A (Lp(a)) (above/below threshold). Indicate threshold.

- Liver damage/hepatitis
- Low-density lipoprotein cholesterol (LDL-C) (above/below threshold). Indicate threshold.

- Lymphopenia
- Mesenteric ischemia
- Metabolic syndrome
- Mortality (All-cause)
- Myocardial infarction (All types)
- Myocardial infarction (Fatal)
- Myocardial infarction (Non-fatal)
- Nausea
- Nausea and Vomiting (combined)
- Neurologic adverse events (All types)
- Neuropathy
- Neutropenia
- Non-HDL-C. specify threshold

- Obesity
- Organ toxicity
- Percutaneous transluminal coronary angioplasty (PTCA/PCI/stenting)
- Peripheral revascularization (+/- stent)
- Platelet aggregability (above/below threshold). Indicate outcome and threshold.

- Prolonged QT interval

- Prothrombin time (above/below threshold). Indicate threshold.

- Quality of Life
- Rash
- Ratio of BUN/creatinine (Raised)
- Renal replacement therapy (e.g. dialysis)
- Seizures
- Serious adverse events (composite outcome)
- Stroke (All types)
- Stroke (Fatal)
- Subretinal hemorrhage
- Sudden death
- Syncope
- Thrombocytopenia

- Thrombotic/Ischemic stroke
- Total cholesterol (above/below threshold). Indicate threshold. _____
- Transient ischemic attack (TIA) _____
- Triglycerides (above/below threshold). Indicate threshold. _____
- Unstable angina
- Valve replacement
- Valvular disease. Please specify outcome. _____
- Vascular death
- Ventricular fibrillation
- Ventricular tachycardia
- Vomiting
- Withdrawal due to adverse events
- Other. Please specify _____

2. Definition of outcome if reported:

3. Other description of outcome:

4. Pooled Data (Pre + Post cross over)

Pooled Supplement (select one)

- | | | |
|---|--|--|
| <input type="checkbox"/> Coenzyme Q10 | <input type="checkbox"/> Ginseng | <input type="checkbox"/> Resveratrol |
| <input type="checkbox"/> Echinacea | <input type="checkbox"/> Hawthorn | <input type="checkbox"/> Vitamin A |
| <input type="checkbox"/> Fish/marine oils | <input type="checkbox"/> Magnesium | <input type="checkbox"/> Vitamin D |
| <input type="checkbox"/> Garlic | <input type="checkbox"/> Niacin | <input type="checkbox"/> Vitamin D + Calcium |
| <input type="checkbox"/> Ginger | <input type="checkbox"/> Omega-3 (EPA, DHA, or both) | <input type="checkbox"/> Vitamin E |
| <input type="checkbox"/> Gingko biloba | <input type="checkbox"/> Red yeast rice | <input type="checkbox"/> Vitamin K |
| <input type="checkbox"/> Other supplement (intervention group). Please specify. | | _____ |

N(included) _____
N(analyzed) _____
n1(subjects free of event at baseline) _____
n2(subjects with event) _____
n3(events) _____
n2/N(analyzed) (%)
Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign). _____
Event Risk (n2/n1)(%)
Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign). _____

Pooled Control (select one)

- No treatment (aside from CVD drug)
 - Placebo
 - Other dietary supplement. Please specify.
-

N(included) _____
N(analyzed) _____
n1(subjects free of event at baseline) _____
n2(subjects with event) _____
n3(events) _____
n2/N(analyzed) (%)
Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign). _____
Event Risk (n2/n1)(%)
Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign). _____

ESTIMATES OF GROUP DIFFERENCES

5. Has an adjusted analysis been presented for this outcome?

- Yes. If yes, list the variables that were adjusted for. _____
- No

6. Pre + Post cross over: Mean between group comparisons

Supplement (select one) **VS.**

Control (select one)

- | | |
|--|---|
| <input type="checkbox"/> Coenzyme Q10 | <input type="checkbox"/> No treatment (aside from CVD drug) |
| <input type="checkbox"/> Echinacea | <input type="checkbox"/> Placebo |
| <input type="checkbox"/> Fish/marine oils | <input type="checkbox"/> Other dietary supplement.
Please specify. _____ |
| <input type="checkbox"/> Garlic | |
| <input type="checkbox"/> Ginger | |
| <input type="checkbox"/> Gingko biloba | |
| <input type="checkbox"/> Ginseng | |
| <input type="checkbox"/> Hawthorn | |
| <input type="checkbox"/> Magnesium | |
| <input type="checkbox"/> Niacin | |
| <input type="checkbox"/> Omega-3 (EPA / DHA / both) | |
| <input type="checkbox"/> Red yeast rice | |
| <input type="checkbox"/> Resveratrol | |
| <input type="checkbox"/> Vitamin A | |
| <input type="checkbox"/> Vitamin D | |
| <input type="checkbox"/> Vitamin D + Calcium | |
| <input type="checkbox"/> Vitamin E | |
| <input type="checkbox"/> Vitamin K | |
| <input type="checkbox"/> Other. Please specify.
_____ | |

Crude Event Risk Ratio	_____	Adjusted Event Risk Ratio	_____
95% CI - lower	_____	95% CI – lower	_____
95% CI - upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____
Crude Event Odds Ratio	_____	Adjusted Event Odds Ratio	_____
95% CI – lower	_____	95% CI – lower	_____
95% CI – upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____

COMMENTS