

DSCI: Continuous 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.

- Activated partial thromboplastin time (aPTT)
- Aggregation time
- Alanine transaminase (ALT)
- Anemia: Other parameter (e.g. ferritin, MCV, MCH). Specify outcome. _____
- Anemia: Serum iron level
- Ankle-brachial index
- Area under the concentration curve (AUC)
- Arterial blood pressure
- Aspartate aminotransferase (AST)
- Bioavailability (F)
- Bleeding time
- Blood urea nitrogen (BUN)
- Body mass index (BMI)
- Carotid intima-media thickness (IMT), as measured by Doppler ultrasound
- Change in 10-year Framingham risk profile
- Clearance (Cl: volume of blood cleared of drug per unit time)
- Clotting time
- Concentration of drug transport proteins
- Coronary/cerebral arterial calcification score
- C-reactive protein (CRP)
- Creatinine
- Diastolic blood pressure (DBP)
- Ejection fraction
- Elimination rate constant (Kel) or Fraction of drug eliminated per unit time

- Fasting blood glucose
 - Glomerular filtration rate (GFR)
 - Glycosylated hemoglobin (HbA1c)
 - Half-life (T1/2)
 - High-density lipoprotein cholesterol (HDL-C)
 - International normalized ratio (INR)
 - Leukpenia: WBC count
 - Lipoprotein A (Lp(a))
 - Low-density lipoprotein cholesterol (LDL-C)
 - Lymphopenia: Lymphocyte level
 - Maximum concentration (Cmax)
 - Neutropenia: Neutrophilic granulocyte count (ANC)
 - Non-HDL-C
 - Platelet aggregability. Specify outcome. _____
 - Platelet count
 - Prothrombin time (PT)
 - Quality of Life
 - Ratio of BUN/creatinine
 - Systolic blood pressure (SBP)
 - Time to reach maximum concentration (Tmax)
 - Total cholesterol
 - Triglycerides
 - Volume of distribution (Vd)
 - Other. Please specify.
-

2. Definition of outcome (optional – if reported):

3. Other description of outcome:

4. Units: _____

5. 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)	_____	Mean Change	_____	% change in mean	_____
N(analyzed)	_____	SD	_____	SD	_____
Mean	_____	SE	_____	SE	_____
SD	_____	95% CI – lower	_____	95% CI – lower	_____
SE	_____	95% CI – upper	_____	95% CI – upper	_____
		p-value	_____	p-value	_____

Pooled Control (select one)

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

N(included)	_____	Mean Change	_____	% change in mean	_____
N(analyzed)	_____	SD	_____	SD	_____
Mean	_____	SE	_____	SE	_____
SD	_____	95% CI – lower	_____	95% CI – lower	_____
SE	_____	95% CI – upper	_____	95% CI – upper	_____
		p-value	_____	p-value	_____

ESTIMATES OF GROUP DIFFERENCES

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

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

7. Mean between group differences: Crude estimates

Supplement (select one) VS.

- Coenzyme Q10
- Echinacea
- Fish/marine oils
- Garlic
- Ginger
- Gingko biloba
- Ginseng
- Hawthorn
- Magnesium
- Niacin
- Omega-3 (EPA / DHA / both)
- Red yeast rice
- Resveratrol
- Vitamin A
- Vitamin D
- Vitamin D + Calcium
- Vitamin E
- Vitamin K
- Other. Please specify.

Control (select one)

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

Crude Difference
in Means⁺

SD _____
SE _____
95% CI - lower _____
95% CI - upper _____
p-value _____

Crude Difference in
% mean change⁺

SD _____
SE _____
95% CI - lower _____
95% CI - upper _____
p-value _____

Crude mean ratio⁺⁺

SD _____
SE _____
95% CI - lower _____
95% CI - upper _____
p-value _____

⁺ Pre + post cross over

⁺ Mean(treatment)/Mean(control) Indicate as a ratio, not a fraction.

8. Mean between group differences: Adjusted estimates

Supplement (select one) **VS.**

- Coenzyme Q10
- Echinacea
- Fish/marine oils
- Garlic
- Ginger
- Gingko biloba
- Ginseng
- Hawthorn
- Magnesium
- Niacin
- Omega-3 (EPA / DHA / both)
- Red yeast rice
- Resveratrol
- Vitamin A
- Vitamin D
- Vitamin D + Calcium
- Vitamin E
- Vitamin K
- Other. Please specify.

Control (select one)

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

Adjusted
Difference in
Means⁺

SD

SE

95% CI - lower

95% CI - upper

p-value

Adjusted Difference
in % mean change⁺

SD

SE

95% CI – lower

95% CI – upper

p-value

Adjusted mean
ratio⁺⁺

SD

SE

95% CI – lower

95% CI – upper

p-value

⁺ Pre + post cross over

⁺⁺ Mean(treatment)/Mean(control) *Indicate as a ratio, not a fraction.*

9. Do the measures of dispersion (SE/SD/95%CI) reported for this outcome include within patient differences?

- Yes
 - No
 - Unclear
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COMMENTS