Title of Research
Cholesterol Treatment Trialists' (CTT) Collaboration: Analyses of Adverse Event Data from Randomized Controlled Trials of Statin Therapy

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Summary of Research
The aim of the proposed analyses is to provide a more complete understanding of the nature and magnitude of any adverse effects of statin therapy, and to compare these to their benefits, in different circumstances.

This will build on work by the Cholesterol Treatment Trialists' (CTT) Collaboration (https://www.cttcollaboration.org), set up in 1994 after it was recognized that any single lipid intervention trial would be unlikely to have a sufficient number of participants (and hence statistical power) to reliably assess mortality outcomes or look at events in specific types of patient. The CCT Collaboration's aim is to conduct periodic meta-analyses of large-scale (≥1000 participants), long-term (≥2 years scheduled treatment duration) unconfounded, randomized controlled trials of lipid intervention therapies. The group's work to date has mainly focused on statin therapy, with collection of individual participant data on major vascular events, cancers and mortality from around 30 major statin trials (involving some 175,000 trial participants). These analyses have added to the body of evidence for the efficacy and safety of statins.

Study Design
This study will involve meta-analyses, a type of epidemiological study design that systematically assesses the results of previous research to draw conclusions about that body of research. Outcomes from a meta-analysis may include a more precise estimate of the effect of treatment or risk factor for disease, or other outcomes, than any individual study contributing to the pooled analysis. These meta-analyses will be based on randomized, controlled clinical trials.

Study Population
Randomized trials of statin therapy will be included in these analyses if they meet the original criteria set by CTT Collaboration. For example, there should be no confounding with respect to the statin comparisons, meaning that there were no other intended differences in risk factor modification between the randomized treatment groups; and the trials must have recruited at least 1,000 participants for a scheduled study treatment duration of at least two years.

Funding Source of Research
The CTT Collaboration work has received grants from governmental organizations (the UK Medical Research Council, Australian National Heart Foundation, and Australian National Health and Medical Research Council) and from charities (British Heart Foundation, Cancer Research UK, and Australian National Heart Foundation) but not from the pharmaceutical industry.

Requested Study
CV123-229 (NCT00382460): Pravastatin or Atorvastatin Evaluation and Infection Therapy (TIMI22)