HPS2-THRIVE: Treatment of HDL to Reduce the Incidence of Vascular Events

Appendix

Study organisation

The HPS2-THRIVE study was designed and is being conducted and analysed by the CTSU at Oxford University, which is the independent regulatory sponsor and retains the study database for all analyses (including regulatory submissions). It is an international collaboration with the China Oxford Centre for International Health Research in Beijing, China, and investigators in Denmark, Finland, Norway and Sweden. The study is funded by a grant to Oxford University from Merck (manufacturers of the study drugs) to cover the costs of central coordination and all costs in the UK and China, with direct funding provided by Merck to its subsidiaries in the Scandinavian countries to cover their local study costs. Packaged ERN/LRPT and matching placebo tablets, and simvastatin and ezetimibe/simvastatin tablets, were provided by Merck direct to the local sites. The study Steering Committee includes representatives from the regions, cardiologists, clinical trialists, statisticians and non-voting observers from the funder. An independent Data Monitoring Committee reviewed the data at 6 monthly intervals and was to inform the Steering Committee if, in their view, the randomized comparisons in the study had provided both (a) proof "beyond reasonable doubt" that for all, or some specific types of, patients prolonged use of ER niacin/laropiprant is clearly indicated or clearly contraindicated; and (b) evidence that might reasonably be expected to influence materially the patient management of many clinicians who are already aware of the results of other studies. The Data Monitoring Committee did not make any such recommendation and the study continued to its scheduled end.

Central laboratory assays

In the UK, the samples were couriered overnight at 4°C to the central laboratory; in the other regions, samples were processed at the local sites and stored at -40°C or below before frozen transfer to the central laboratory in Oxford. Creatinine and lipids (total cholesterol, LDL-C, HDL-C, TG, apoB and apoA1) in lithium heparin plasma, glucose in fluoride oxalate plasma, and creatinine and albumin in

urine were assayed using Beckman-Coulter LX20 and DxC800 clinical chemistry analysers and manufacturers' reagents, calibrators and settings (Beckman-Coulter, UK), except LDL-C and HDL-C which used N-geneous reagents, calibrators and settings (Genzyme Diagnostics, UK). Glomerular filtration rate was estimated using the CKD-EPI formula (1). HbA1c analysis was performed by HPLC using EDTA whole blood on an Arkray HA8160 analyser and reagents with a calibrator supplied by Menarini Diagnostics UK traceable to IFCC and DCCT reference standards. Blood counts were performed using a Coulter Gen-S analyser with manufacturers' reagents, calibrators and settings. All assays were performed in the central laboratory at the CTSU using methods accredited by the UK Accreditation Service, except HbA1c analysis for Chinese samples which were done in Beijing with quality oversight by the CTSU laboratory and Lp(a) measures which were performed at the Northwest Lipid Metabolism And Diabetes Research Laboratories, Seattle, USA.

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