

University of Oxford
12:00 BST 02 September 2013

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HPS3/TIMI55 – REVEAL trial of Anacetrapib in high-risk vascular patients recruits the target of 30,000 participants

The REVEAL (Randomized Evaluation of the Effects of Anacetrapib through Lipid-modification) trial is investigating whether a drug called anacetrapib can drive down the risks of coronary deaths, heart attacks, and other vascular complications.

The study has now reached its recruitment target of 30,000. This includes over 15,000 people in Europe, 6,000 in North America and 8,000 in China. It is anticipated that the results will become available in 2017.

Anacetrapib is an investigational cholesterol treatment, belonging to a drug class known as CETP (Cholesteryl Ester Transfer Protein) inhibitors, which is being developed by MSD (known as Merck in the US and Canada). In previous studies, anacetrapib produced significant reductions in blood levels of 'bad' LDL cholesterol in addition to those achieved with statin drugs, and it more than doubled 'good' HDL cholesterol levels.

Dr Martin Landray of Oxford University, one of the co-principal investigators of REVEAL, said:

"Since the end of 2011, over 30,000 patients have entered the REVEAL study. This impressive rate of recruitment – at its peak, over 1,000 patients per week for 8 consecutive weeks - reflects the high level of enthusiasm among clinicians and patients to study this important question. We are grateful to all of them for their hard work and commitment."

Dr Louise Bowman of Oxford University, the other co-principal investigator, said:

"Anacetrapib has large effects on blood levels of cholesterol and appears to be well tolerated. The REVEAL study will address the critical issue of whether these biochemical changes translate into reductions in coronary deaths and heart attacks."

End

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Notes:

REVEAL involves 30,000 men and women aged at least 50 with a history of heart attack, stroke or peripheral arterial disease. All study participants will be given atorvastatin (a commonly used 'statin' drug) to ensure good control of LDL ('bad') cholesterol. In addition, they will be randomly allocated to receive anacetrapib or matching placebo (dummy) tablets daily for at least 4 years. The primary objective of the study is to see whether fewer participants given anacetrapib have heart attacks, revascularisation procedures or die from coronary heart disease than do those in the placebo arm.

An international Steering Committee is responsible for overseeing the study's progress, and an independent Data Monitoring Committee is responsible for the on-going review of the emerging study results (including both safety and efficacy).

The Clinical Trial Service Unit (CTSU) at Oxford University has designed the REVEAL study and is responsible for coordinating it and for analysing its results, independently of the funder (MSD). The CTSU is well known for running huge international studies, including the ground-breaking Heart Protection Study which showed that a third of all heart attacks and strokes can be safely avoided in people at risk of vascular disease by using statins to lower bad 'LDL' cholesterol. The CTSU also showed that more intensive lowering of LDL cholesterol with statins produces extra benefits.

CTSU receives core funding from the Medical Research Council, British Heart Foundation and Cancer Research UK. The REVEAL trial is funded through a grant to Oxford University by the pharmaceutical company Merck Sharp & Dohme Corp. (Whitehouse Station, NJ, USA), developers of anacetrapib. CTSU has designed the study and will be responsible for coordinating it and for analysing its results, independently of the study funder. REVEAL will test the treatment's effectiveness and safety.

More information on the REVEAL trial is available from:

clinicaltrials.gov/show/NCT01252953

www.controlled-trials.com/ISRCTN48678192

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