STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No drug

ACTIVE INGREDIENT: No drug

Study No: NIS-CSE-CRE-2011/1, NCT number NCT01551784
An observational study of statin treatment induced HDL changes – effect on cardiovascular disease – SIRIUS

Developmental Phase: Observational study
Study Completion Date: 9 Oct 2012
Date of Report: 9 Oct 2013

OBJECTIVES:

The primary objective of this explorative study was to investigate the effect of statin induced changes in HDL-C on a composite endpoint including unstable angina pectoris, myocardial infarction and ischemic stroke with adjustment for changes in other blood lipids and clinical parameters

METHODS:

The aim was to investigate 120,000 subjects with baseline- and follow-up cholesterol variables. Data were to be extracted from 3 countries; Sweden (medical records from primary care and national registers), the Netherlands (PHARMO) and United Kingdom (GPRD and IMS Disease Analyzer).

The data from the different countries showed a large variability due different reimbursement requirements for prescribing statins and register structure, and only data from Sweden was analyzed in order to reduce number of confounders.

Patients initializing statin treatment during 2004-2010 were identified at 76 primary care centers, their clinical data collected and merged with data from the national drug register, the national hospital register and the cause of death register in Sweden. Applying conditions of at least two lipid measurements, age between 18-85 years, >15 months of medical history, yielded a cohort of 19 983 patients. Two propensity score matched populations were created, one population that decreased >0.1 mmol in HDL-C/L and one with no change in the HDL-C concentration. Time to first cardiovascular disease (CVD) event (myocardial infarction, unstable angina pectoris, stroke or death) was compared using a Cox regression. The patients were followed until the end-of-study or death.

RESULTS:

Thirty two percent (n=6488) of patients initiated on statins decreased their HDL-C. Of the eligible patients, 10 152 were matched in propensity score analysis and followed for up to 7 years (median 2.6 years) a total of 28 610 patient years. The baseline HDL-C was 1.49 mmol/L and the LDL-C was 4.40 mmol/L in the unchanged and decrease groups. Compared to the unchanged HDL group (n=5056) the risk of CVD was 27% higher in the decreased group (n=5056) (HR 1.27 (95% CI; 1.08-1.49, p = 0.0034)). Simvastatin was the most frequently used statin; 95%.