AstraZeneca

Clinical Study Results Posting Template

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Posting Results:

☐ Study in patients with a serious or life-threatening disease or condition

☒ Hypothesis-testing study in any indication

☐ Non-interventional study with an approved AZ medicine

1. Titles and Background Information

- Protocol ID: 4522AS/0003
- Secondary ID:
- Official Title: *A randomised, double-blind, placebo-controlled, crossover pilot study to define the high density lipoprotein cholesterol (HDL-C)-raising mechanism of rosuvastatin (CRESTOR™) by quantifying the key steps of reverse cholesterol transport (RCT)*
- Finished Product: Crestor
- Active Ingredient: rosuvastatin
- Study Phase: Phase IIIb
- Study Status: completed
- Condition/Disease: Metabolic Syndrome / Dyslipidaemia

2. Key Study Dates

- Study Start Date: 8 August 2003
- LSLV Date: 21 December 2004

- Database Lock: 1 April 2006
- Approval Date: 10 January 2007

3. Objectives

1. Primary Outcome

   Determine the effect of treatment with rosuvastatin on the capacity of plasma to promote cholesterol efflux, which is the first and likely rate limiting step in reverse cholesterol transport.

2. Secondary Outcome

   Determine the effect of treatment with rosuvastatin on:

   - cholesterol esterification by measuring plasma lecithin:cholesterol acyl transferase concentration and capacity to esterify cholesterol, one of the stops in RCT.
   - plasma concentration of cholesterol ester transfer protein and capacity to transfer cholesterol from HDL-C to apoB-containing lipoproteins, one of the steps in RCT.
   - plasma concentration of preβ_1-HDL.
   - plasma concentration of LDL cholesterol, HDL-C and apoA-1.

4. Methods

The purpose of this study was to investigate the effect of treatment with rosuvastatin on the capacity of plasma to promote cholesterol efflux, which is the first and likely rate limiting step in reverse cholesterol transport. 15 patients were entered into the study of which 13 patients were randomised and completed the study.

- Inclusion Criteria:

  Signed informed consent, males aged 45-65, insulin resistance, central obesity, LDL-C <6 mmol/L, plasma triglycerides ≥1.7 and ≤5.5 mmol/L, HDL-C ≤1.2 mmol/L.

- Exclusion Criteria:

  Key exclusion criteria include total cholesterol >7mmol/L, pre-existing cardiovascular disease, diabetes, proteinuria or renal failure, plus others.

5. Results

See publication

6. **Reference**: Published

Citation: Sviridov D, Hoang A, Ooi E, Watts G, Barrett PH, Nestel P. Indices of reverse cholesterol transport in subjects with metabolic syndrome after treatment with rosuvastatin. Atherosclerosis [Epub ahead of print] 2007 Aug 20; DOI: 10.1016/j.atherosclerosis.2007.07.007. Available from: URL:http://www.atherosclerosis-journal.com/article/PIIS0021915007004522/abstract

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