AstraZeneca

**STUDY REPORT SUMMARY**

**ASTRAZENECA PHARMACEUTICALS**

**FINISHED PRODUCT:** Crestor
**ACTIVE INGREDIENT:** Rosuvastatin

| **Study No: NIS-CCH-CRE-2007/1** |
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| C-Control<br>Effect of Rosuvastatin in new and pre-treated patients requiring statin treatment |

**Developmental phase:** NIS
**Study Completion Date: 01.2008**
**Date of Report:** 16.07.2008

**OBJECTIVES:**

The main objective of this survey was to evaluate the efficacy of statins, in particular Crestor® (rosuvastatin) in either naïve or pre-treated patients requiring treatment for hypercholesterolemia with a statin.

**METHODS:**

Open non-randomized survey, without control group.

**RESULTS:**

Demography: 56.1% (1851) patients were males and 43.4% (1431) females. The distribution of genders by therapy and prevention was different, with more males (47.9%) in “change”therapy compared to females. The median age was 58 years in males for 63 years in females.
Rosuvastatin dose: At visit 1, the median Rosuvastatin dose was 10 mg (5 to 50). No evaluation of the change of dose was made due to the high proportion of missing information at visits 2 and 3.
LDL: At visit 1, the median LDL was 4.32 mmol/l (0.2 to 10.20), of which 179 (5.4%) patients were <2.6 mmol/l (Table 39). Significant differences between genders, age, BMI, therapy, and prevention were found. At end-point, the median LDL was 2.7 mmol/l (0 to 7.95).

The median change between v1 and end-point was highly significant with -1.51 mmol/l (-8.2 to 3.28) representing a median decrease of 35.8% (-100% to 535%). The LDL decreased between visit 1 and end-point for 2909 (88.2%) patients, remained unchanged for 13 (0.4%), and increased for 142 (4.3%) patients. At end-point, 1157/3297 (35.1%) patients had a value <2.6 mmol/l which was ⩾2.6 mmol/l at v1. Another 1740 (52.8%) had a value which remained ⩾2.6 mmol/l. The median LDL decrease was significantly higher in new therapy with -39.9% or -1.8 mmol/l compared to -31.7% or -1.26 mmol/l in therapy change. The median reduction in LDL was with -36.6% or -1.6 mmol/l significantly higher in prevention I compared to -33.4% or -1.32 mmol/l in prevention II.
Evaluation: the treatment was assessed as very good in 1912 (58%) patients, as good in 854 (25.9%), satisfactory in 234 (7.1%) and insufficient in 156 (4.7%). The proportion of very good assessments was higher in newly treated patients (42.7%) compared to treatment change (36.4%). The assessments in prevention I and prevention II patients were comparables.
Safety: a total of 199 patients reported one or more AE. The proportion of patients with AE was 5.2% in new therapy, 6.6% in therapy change, 5.3% in prevention I, and 7.2% in prevention II. The proportion of patient with AE was 5.4% in patients with and without comedication.
Overall, the change in LDL was significant and possibly more pronounced in newly treated patients.