AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A
ACTIVE INGREDIENT: N/A

Study No: NIS-CKR-DUM-2009-3
***RACHEL* study** **Investigation into the RAtio of LDL-CHolestEroL to HDL-Cholesterol improvement after statin treatment in Korean patients**

Developmental phase: Marketed
Study Completion Date: 2009-09-18
Date of Report: 2009-11-26

OBJECTIVES:

Primary objectives
To evaluate current LDL/HDL ratio in Korean patients (between baseline & after treatment)

Secondary objectives
To evaluate difference of LDL/HDL ratio among different statins & dosages (between baseline & after treatment)

METHODS:

Design
The present study was a multi-centre survey of subjects who had been diagnosed for dyslipidaemia in tertiary-care hospitals in Korea. This study was conducted retrospectively. Investigators engaged in this study screened their outpatients with their medical chart. After screening appropriate subjects in the past 6 months according to inclusion criteria, investigators filled the patient record form based on medical chart.

Investigators completed a patient record form with subjects' demographic characteristics, lab profile, current medication for dyslipidaemia, CHD risk factors and concomitant medication.

Number of subjects

Approximately 3,000 subjects planned to be recruited from tertiary-care hospitals located in Korea.

Inclusion criteria
For inclusion in this study, subject should fulfil all of the following criteria.
1. Subjects of either gender / aged over 18 years
2. Subjects who are taking lipid-lowering medication after diagnosed as dyslipidaemia

3. Subjects who have at least made 1 visit to the outpatient clinic within previous 6 months
4. Subjects who have records of both LDL-C and HDL-C before & after statin treatment (at least four weeks after statin taking)

Exclusion criteria

1. Involvement in the planning and conduct of the study (applies to both AstraZeneca staff or staff at the study site).
2. Previous enrolment or randomisation of treatment in the present study.
3. Participation in a clinical trial during the last 90 days.
4. Subjects who are unwilling or unable to provide their examination and lab result of medical chart.

Result variables

- **Primary variables:** LDL/HDL ratio in Korean patients

Statistical Analysis

The design of this study was descriptive and it had no predefined hypothesis. We summarized the data using descriptive statistics and analysis the data with exploratory method about any doubtable factors for primary objective. For comparing among groups, we used 5% significance level. And we made tables and figures for descriptive analysis such as demographic characteristics, Lipid profile.

RESULTS:

A total of 3086 patients from 47 centers participated in this study, of whom 32 patients were excluded from the analysis set as their treatment period of statin was less than 3 weeks (21 day). So 3054 patients were included in the analysis set.
Among 3054 patients, 1718(56.3%) were males and 1336(43.7%) were females. The mean age was 60 years.
The most commonly taken kind of statin was Rosuvastatin(64.3%), followed by Atorvastatin(20.7%).
The ratio of LCL-C and HDL-C was decreased by 0.67~1.91 and the HDL had the biggest impact in the changed value. After the treatment of statin, the ratio of LDL-C and HDL-C was decreased by 1.27.
The mean decrease of the LDL-C/HDL-C in the Rosuvastatin treatment group was 1.37 so highest among the other treatment groups (Simvastatin 1.22, Atovastatin 1.15 and Pitavastatin 0.71).