AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not Applicable
ACTIVE INGREDIENT: Not Applicable

Study No: NIS-SA-CRE-2009/01 (NIS-CZA-DUM-2009/1)
CEPHEUS Centralized pan-South African Survey on the under treatment of hypercholesterolemia

Developmental phase: Phase IV – Non Interventional Survey
Study Completion Date: Last Subject Out: 23 April 2010
Date of Report: 27 October 2010

OBJECTIVES:

Primary

- To establish the proportion of patients on lipid-lowering pharmacological treatment reaching the LDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III.

Secondary

- To establish the proportion of patients on lipid-lowering pharmacological treatment reaching the LDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III in the following sub-populations:
  - Primary/secondary prevention patients,
  - Patients with metabolic syndrome (according to NCEP III definition).
- To establish the proportion of patients on lipid-lowering pharmacological treatment reaching the LDL-C goals according to the Fourth Joint European Task Force guidelines / South African guidelines, in the survey population and in the following sub-populations:
  - Primary/secondary prevention patients
  - Patients with metabolic syndrome.
- To establish the proportion of patients on lipid-lowering pharmacological treatment reaching the non HDL-C goals according to the NCEP ATP III / updated 2004 NCEP

ATP III guidelines < 130 mg/dL (3.36 mmol/L), in the sub-population patients with fasting triglycerides > 200 mg/dL (2.26 mmol/L).

- To identify determinants (e.g. patient and physician characteristics, country-specific guidelines or recommendations) for undertreatment of hypercholesterolemia. Undertreatment is defined as receiving lipid-lowering pharmacological treatment and not reaching the LDL-C goals according to the NCEP ATP III/ updated 2004 NCEP ATP III / Fourth Joint European Task Force guidelines.

To explore physician characteristics associated with the allocation of treatment regimen.

METHODS:

This was a multi-centre survey of patients, in South Africa, on lipid-lowering pharmacological treatment for at least three months and with no dose change for a minimum of six weeks. Patients who came in for their regular scheduled visit to the clinic were consecutively selected and invited to participate in the survey. Data collection took place at a single visit.

Before assessment of any patient, each investigator completed one Investigator Questionnaire on his / her experience and perception of the management of hypercholesterolaemia seen in his / her patients. The investigator indicated his / her general attitude on diagnosis of hypercholesterolaemia, guidelines and goals, and the various treatment options for hypercholesterolaemia.

Before being assessed by the investigator, subjects recorded on a Patient Questionnaire their awareness of hypercholesterolaemia, their current lipid-lowering treatment schedule, perception and compliance.

The investigator completed a Patient Record Form with the patient's demographics, current lipid-lowering drug treatment and the reason for the current therapy. In addition, the investigator recorded the known cardiovascular risk factors and the cardiovascular medical history. A fasting blood sample was taken during the visit or within the next 2 to 5 days to evaluate the blood lipid profile and glycaemia.

Target subject population and sample size

To be included in the survey the subject had to fulfil all of the following criteria:

- 18 years of age or older of either gender or race.
- Provided informed consent and willing to comply with the survey procedures.
- On lipid-lowering drug treatment for at least three months, with no dose change for a minimum of 6 weeks.

Number of subjects planned in South Africa: 3000
Number of subjects consented in South Africa: 3001

RESULTS:

Overall, the results of this survey highlight the suboptimal management of lipid-lowering treated patients. Despite the widespread awareness and implementation of the most recent practice guidelines (2004 updated NCEP ATP III guidelines and the Fourth Joint European Task Force / South African guidelines) and the broad use of statins among lipid-lowering therapy eligible patients the percentage of patients attaining their LDL-C goal does not exceed 60.5%. This percentage is much lower among patients in secondary prevention, or with Coronary Heart Disease, Peripheral Artery Disease, Cerebrovascular Atherosclerotic Disease, family history of premature CVD and Metabolic Syndrome. Among all the patient factors assessed for being putative predictors of LDL-C success, being male, older than 40 years, falling into the lower risk categories, compliance with medication schedule even after cholesterol levels returned to normal, and acknowledging the current cholesterol situation were associated with the highest probability to attain the LDL-C goal recommended by the NCEP ATP III / 2004 updated NCEP ATP III guidelines and Fourth Joint European Task Force / South African guidelines. Physician factors that were predictive of successfully achieving LDL-C goals according to all the guidelines assessed included male physicians, with an attitude of agreeing that sufficient patients meet goal, and that do not feel constrained by funder re-imbursement formularies in their choice of lipid-lowering treatment.

A greater effort should be put forward to early diagnose subjects with Coronary Heart Disease risk so that they can be treated accordingly. Moreover, physicians should encourage their patients to undertake lifestyle changes including a healthier diet, regular exercise and weight loss. In addition, patients should be better informed on the importance of treatment compliance in order to increase its effectiveness.