AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Statins
ACTIVE INGREDIENT: N/A

Study No: NIS-CTW-CRE-2007/1

A Non-interventional, Multicentre, Open-label, Prospective, Phase IV Study to Explore the Treatment Effect of Various Commercially Available Statins on Patients with Hyperlipidemia

Developmental Phase: IV
Study Completion Date: 24 Nov 2009
Date of Report: 3 Nov 2010

OBJECTIVES:

Primary
The primary objective is to survey the efficacy of various commercially available statins (a class of lipid-lowering agents, for example, rosuvastatin, atorvastatin, simvastatin, lovastatin, pravastatin and fluvastatin) under local clinical practice in treating patients with hyperlipidemia. Surveillance data (Lipid Profile) will be collected during course of usual clinical practice or captured upon its availability.

Secondary

- Treatment-to-goal ratios at 6 months
- Compliance for taking antihyperlipidemic medication.
- Physician's and patient's insight into the necessity and the urgency of hyperlipidemia treatments
- The impact of physician's or patient's insight on patients' treatment compliance, and the treatment-to-goal ratios

METHODS:

This is a non-interventional, multicentre, open-label, Phase IV study to evaluate the efficacy of various commercially available statins on patients with hyperlipidemia and the relationship between patients' education, patients' insight, and treatment outcome. Eligible patients who is newly initiated with statins, switched to new statins, or newly adjusted dosage of statin will be enrolled. All patients will be provided with the follow-up program including the patient education upon enrollment through using of the educational

booklet with the Framingham Heart Study Prediction Score Sheets, and reminding of visiting schedule according to routine practice. The prediction of CV risk from Framingham Heart Study Prediction Score Sheet will be conveyed to the patients. The study procedures will clearly fall within normal clinical practices that patients are prescribed by their physician of commercially available statins ahead of study enrolment. The study observational period for each enrolled patient will be 3~6 months. The clinical and laboratory data will be collected in a non-interventional manner at the date of patient entry, and subsequently at 3~6 months post enrolment. Physician's insight will be collected once upon investigators' initiating meeting by questionnaires. Patient's insight will be probed by questionnaires twice, firstly at study enrolment and secondarily at 3~6 months post enrollment.

This surveillance study imposes no investigational interventions to the naturalistic approach of the management of hyperlipidemia. The investigator will follow their usual clinical practice and prescribe the medications deemed necessary for the safety of the patients. Surveillance data will be collected during course of usual clinical practice or captured upon its availability.

RESULTS:

A total of 3270 patients were enrolled at 17 medical centers. The mean age, waist, weight and gender distribution (male: female) were 61.35 ± 11.32 years old, 89.03 ± 13.29 cm, 67.48 ± 12.25 kg, and 52%: 48%, respectively. A total of 3197 patients completed the study.

Lipid Profile

In this study, a reduction in LDL-C, HDL-C, TC lipid profile, triglycerides level and fasting glucose of -45.61 ± 42.24 mg/dL; -2.23 ± 34.76 mg/dL; -54.93 ± 49.40 mg/dL; -25.43 ± 126.74 mg/dL; and -4.43 ± 49.69 mg/dL was observed in all treatment groups from baseline until end of study respectively.During the study, LDL-C and TC reduction in rosuvastatin group were observed statistical significantly with other statins ($p<0.05$).

Treatment to Goal and Treatment to Compliance

The proportion of patients reaching the treatment to goal for rosuvastatin, atorvastatin, lovastatin, simbastatin, fluvastatin, and pravastatin was 77% , 75%, 76%, 73%, 65%, and 59% respectively. Apparently, statistically significant difference ($p<0.001$) was observed across all statin groups with respect to treatment to goal achievement.
In compliance evaluation patients who seldom or forgot to take medicine once time per week was 90%, 89%, 91%, 85%, 79%, and 85% for rosuvastatin, atorvastatin, simvastatin, lovastatin, pravastatin and fluvastatin, respectively. Patients who forgot to take medicine twice or 3 times per week was 7%, 7%, 4%, 11%, 14%, and 11% for these statins, respectively. Patients who forgot to take medicine more 3 times per week was 3%, 4%, 4%, 5%, 7%, and 4% respectively ($p=0.105$).

Physician's and Patient's Insight into the Necessity and Urgency of Hyperlipidemia

Treatments

Over 71% physicians agreed that trust the prescription from physicians while 73% agreed that understanding the risk of coronary heart risk are important for patient's continuously good compliance. Additionally, physicians agreed that the level from laboratory test of blood lipid (61%), no bothering side effects from medication (41%), previous family history of incidence of cardiovascular disease (55%) are also important factors to consider evaluating patient compliance to statin treatments.

Physicians agreed that patients must be informed about the values/results of their lipid profile. During the study, values/results of TC, LDL-C, HDL-C and TG values were informed to 94.73%, 92.67%, 82.20%, and 90.80% respectively. Additionally, approximate 40% of patients were explained the predication coronary heart risk in future 10 years. Furthermore, over 70% physicians strongly agreed that explanation to patients was able to improve the treatment compliance and increase the treatment-to-goal. Only 1% physicians did not agree it.

The mean percentage of patients who reached the treatment goal after 3 months was 61.28 ± 17.85% for the Primary Prevention Group and 59.53 ± 19.52% for the Secondary Prevention Group.

The mean percentage of patients who reached the treatment goal after 6 months was 69.45 ± 17.27% for the Primary Prevention Group and 69.77 ± 19.55% for the Secondary Prevention Group.

In comparison with results at pre-study, patient's disease awareness, patient education from physicians, lipid control, and treatment compliance show significant improvement at post-enrollment ($p<0.05$).

Impact of Physician's Insight

In logistic regression analysis, the percentage of patients with primary prevention treatment, percentage of patients with secondary prevention treatment, trust of the prescription from the physicians, understanding of the CHD risk, and previous incidence of cardiovascular disease were associated with the impact of physician's insight on patient's hyperlipidemia treatment
compliance ($p<0.05$). The odds ratio was 0.994, 0.991, 0.790, 0.786, 0.671, and 0.696, respectively. Moreover, understanding of the CHD risk, the level from laboratory test of blood lipid, and somehow physician's agreement on compliance improvement and treatment-to-goal ratios increasing through the CHD risk explanation were associated with the impact of physician's insight on patient's hyperlipidemia treatment-to-goal ($p<0.05$). The odds ratio was 1.255, 1.212, and 1.928, respectively.

Impact of Patient's Insight

At final visit, understanding the CHD risk in the future 10 years, latest LDL-C profile, understanding of the importance of drug treatment for cholesterol control, forgetting to take medication seldom, forgetting to take medication once a week, forgetting to take medication twice a week, and forgetting to take medication three times a week were associated with the impact of patient's insight on patient's hyperlipidemia treatment

compliance ($p<0.05$).
The odds ratio was 1.010, 1.010, 0.993, 0.000, 0.000, 0.004 and 0.052, respectively. Moreover, latest LDL-C profile, treatment goal ranging between 100 to 130 mg/dL, treatment goal ranging between 130 to 160 mg/dL, taking several medication at same time, forgetting to take medication seldom, forgetting to take medication once a week, and forgetting to take medication twice a week were associated with the impact of patient ’ s insight on patient’ s
hyperlipidemia treatment compliance ($p<0.05$). The odds ratio was 0.980, 0.493, 0.407, 1.471, 14.30, 6.055, and 2.360, respectively.