AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

Study No: NIS-CBA-CRE-2011/1
Non-interventional study to assess reaching of cholesterol target values in patients treated with HMG-CoA reductase inhibitors in Bosnia and Herzegovina

Developmental phase: Non-interventional study

Study Completion Date: 01/09/2013

Date of Report: 01/05/2014

OBJECTIVES

Primary:

- To evaluate the proportion of patients treated with HMG-CoA reductase inhibitor for at least 6 months, reaching the LDL-C goals according to the Fourth Joint European Task Force guidelines on Cardiovascular disease prevention in clinical practice.

Secondary:

- To evaluate the proportion of patients, treated with HMG-CoA reductase inhibitor for at least 6 months, reaching the total cholesterol goals according to the Fourth Joint European Task Force guidelines on Cardiovascular disease prevention in clinical practice.
- To evaluate the proportion of patients with high cardiovascular risk (according to definition of Forth Joint European Taskforce), treated with HMG-CoA reductase inhibitor for at least 6 months, reaching the total cholesterol goals according to the Fourth Joint European Task Force guidelines on Cardiovascular disease prevention in clinical practice.
- To evaluate determinants for not reaching LDL-C or total cholesterol goal values.
- To assess compliance with prescribed therapy.

METHODS:

Patient population

Male/female patients, aged 18 years or older who have been treated with one HMG-CoA reducatse inhibitor for at least 6 months without changing the dose for the last 4 weeks at least.

All patients must sign informed consent form.

Design

This is a multi-centre non-interventional study of patients who are treated with HMG-CoA reductase inhibitor in Bosnia and Herzegovina for at least 6 months.

All HMG-CoA reductase inhibitors must be prescribed in accordance with SmPCs approved in Bosnia and Herzegovina.

Patients treated with any HMG CoA inhibitor available in Bosnia and Herzegovina (rosuvastatin, simvastatin, atorvastatin and fluvastatin).

Data collection for each patient will take place at a single visit.

The investigator will complete a Case Report Form with the patient's demographics, the presence of the factors for high cardiovascular risk, current treatment, cholesterol values as well as with further treatment decision.

Study Plan

	Visit 1
ICF	X
Test List	X
Demographic Data (age and gender)	X
Conformation oft he presence of all criteria for inclusion int he study, ie, the absence of exclusion criteria for patients int he study	X

	The presence of disease that indicate a high cardiovasculR RISK ACCORDING TO THE Fourth Taskforce European Society of cardiology in 2007. guidelines	X
	Dana on the lipids levels (total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides)	X
	Dana on achiving target LDL cholesterol and total cholesterol and achieving recommended values of HDL cholesterol and triglycerides	X
	HMG-CoA reduktase inhibitor treatment data	X
	Compliance with the prescribed treatment	X

Study Drug

HMG-CoA reduktase inhibitor

Statistical analysis

All statistical analysis were performed by using the SPSS 13.0 package. Descriptive statistical analysis was also used for evaluation.

RESULTS:

Patients Demographic Data

Patient Demographic Data							
Age		**Up to 29**	**30-39**	**40-49**	**50-59**	**60-69**	**>70**
	Female 335	14	5	16	94	115	55
	Male 342	19	6	38	96	93	54
Overall		33	11	54	190	208	109

The most patients 81.6% were at high risk for CVD. 62.8% had pre-existed coronary heart disease (CHD), 24% had peripheral artery disease (PAD, and 18.7 % had cerebrovascular disease and 41.3% had diabetes mellitus.

High risk for CVD		
	No	%
No	128	18,4%
Yes	569	81,6%
No data	0	0,0%
Total	697	100,0%

Treatment data

The most frequently used statin was rosuvastatin (61.8%), followed by atorvastatin (26.8%) and simvastatin (10.0%). Fluvastatin was taken by only 0.1% of patients while data for 1,1% of patients were not available.

Therapeutic response

33.9 % patients had LDL-cholesterol at goal.

35.2% achieved total cholesterol target, and 69.7% of those with high CVD risk.

39.9% of patients had achived HDL cholesterol target.

55.8% of patients had elevated triglyceride level.

Compliance with the prescribed treatment

The compliance of patients in taking the prescribed statin during 30 days before visiting their cardiologists was 67.7% of them 100%, 20.9% were taking the prescribed statin, 5.7% were taking between 50%-70%, 2.4% were taking between 30-50%, and 1.3% took less than 30%. 0.6% were not taking the prescribed statin at all.

Further treatment advice

The most of the patients on rosuvastain treatment (62.6%) were advised by their cardiologist to continue with the same statin and without changing the dose, while the significantly less patients on atorvastatin (41.2%) and simvastatin (30.9%) received such advice.

Adverse event

No adverse event were reported in this study