A European, observational, three-year cohort comparative study on the safety of the fixed-dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice (POSE)

First published: 29/07/2016

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Study | Finalised

Administrative details

EU PAS number

EUPAS13661

Study ID

38822

DARWIN EU® study

No

Study countries

Greece

Portugal

Spain

Study description

This is a multicentric, European, comparative, partly retrospective and prospective, observational cohort study with a three-year follow up in patients treated with Pravafenix® or with a statin at standard dose in monotherapy. This study is conducted in real clinical practice conditions of prescription designed to obtain further data on the safety and use of Pravafenix® in real conditions of use. Physicians will be GPs, cardiologists, internists and endocrinologists hospital-based or private practice from at least three European countries (Portugal, Spain and Greece). Physicians will be required not to change their typical practice in treating patients. Baseline information will be collected from the medical records at study treatment initiation and follow-up information will be collected over a period of three years according to the visits performed by the physicians.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 150 centres are involved in the study

Contact details

Study institution contact

Sophie DE NIET sdeni@smb.be

Study contact

sdeni@smb.be

Primary lead investigator

Sophie DE NIET

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/05/2016

Study start date

Actual: 20/12/2016

Date of final study report

Planned: 13/09/2023

Actual: 12/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Laboratoires SMB S.A

Study protocol

PRAVAFENIX-POSE study-Protocol -version 1 0 (28 July 2016).pdf (1.18 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective is to compare the incidence rate of the main safety endpoints between patients treated by Pravafenix or by a statin in monotherapy in real clinical practice conditions within a three-year follow-up period.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multicentric, European, comparative, partly retrospective and prospective, observational study

Study drug and medical condition

Medicinal product name

PRAVAFENIX

Medical condition to be studied

Hyperlipidaemia

Dyslipidaemia

Population studied

Short description of the study population

Adults patients aged 18 years or older treated with pravastatin or with a statin used at standard stable dose in monotherapy followed by general practitioners (GPs), cardiologists, endocrinologists, internists in real clinical practice in three European countries.

Inclusion criteria:

§ Adult patients (≥18 years old) currently treated or intended to be treated at time of inclusion with Pravafenix. In case of ongoing therapy at enrolment, treatment with Pravafenix must have started within 12 months prior to ICF signature date.

§ Adult patients (≥18 years old) treated by a statin in monotherapy at stable standard dose for at least 3 months (dosage stability should have started within 12 months prior to ICF signature date). The standard dose of statin is defined by NCEP ATP III as the dose required to attain an approximate 30% to 40% reduction of LDL-C levels; i.e. atorvastatin 10 mg, lovastatin 40 mg, pravastatin 40 mg, simvastatin 20-40 mg, fluvastatin 40-80 mg and rosuvastatin 5-10 mg.

Exclusion criteria:

§ The patients who are participating in other clinical studies concomitantly with this survey will not be included in this study.

§ Concomitant lipid lowering therapies with fibrates.

§ Patients for which no medical records are available at study treatment initiation.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

3.000

Study design details

Outcomes

Safety endpoints will include renal and urinary disorders, musculoskeletal and connective disorders, hepatobiliary disorders, cholelithiasis, thromboembolic events, pancreatitis, diabetes mellitus aggravated, blood homocysteine increase, interstitial pneumopathy and phototoxicity. To compare the time to first occurence of the main safety endpoints, the incidence rate of cardiovascular events, the incidence rate of the laboratory abnormalities. To describe the adverse events, the patients characteristics and treatment history, the physicans characteristics, the pattern of use of Pravafenix and the routine risk minimisation.

Data analysis plan

Descriptive analyses for continuous variables such as the mean, its bilateral 95% CI, standard deviation, median, minimum and maximum values will be presented. For categorical variables, the number and the percentage of patients in each category will be specified. The two-sided 95 % CI will be specified for the categorical evaluation criteria. The proportion of patients with at least one occurrence of safety endpoint will be described for each safety endpoint along with the two-sided 95% CI. Time to event (“event-free survival”) will be estimated using the Kaplan Meier method. The cumulative distribution function will be plotted. Comparative analyses For descriptive purpose, characteristics of

patients at entry will be compared between the two treatment groups. Adjusted and unadjusted absolute and relative risks will be provided based on incidence rates together with 95% CI.

Documents

Study results

POSE_CSR_SYNOPSIS_ver 1.0.pdf (219.12 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, From the patient medical records for the retrospective data.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No