

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

**Last updated:** 05/09/2023

Study

Finalised

## Administrative details

### EU PAS number

EUPAS13661

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### Study ID

38822

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### DARWIN EU® study

No

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### Study countries

 Greece

 Portugal

## 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.

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## 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](mailto:sdeni@smb.be)

### **Primary lead investigator**

Sophie DE NIET

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 18/05/2016

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### **Study start date**

Actual: 20/12/2016

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### **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

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### **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

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##### **Study type:**

Non-interventional study

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##### **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

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**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

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**Non-interventional study design, other**

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

## Study drug and medical condition

**Medicinal product name**

PRAVAFENIX

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**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 ( $\geq 18$  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 ( $\geq 18$  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.

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## **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)
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### **Estimated number of subjects**

3000

## 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 occurrence 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 physicians characteristics, the pattern of use of Pravafenix and the routine risk minimisation.

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### **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)

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## 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](#)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No