Assessment of Health Care Professionals' Knowledge and Behaviour Regarding Prescribing Conditions of Cholib® (fenofibrate and simvastatin fixed combination): A European PASS conducted in Austria, Portugal, Slovenia, Croatia, Greece and Bulgaria

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Study Planned

Administrative details

EU PAS number

EUPAS15741

Study ID

34166

DARWIN EU® study

No

Study countries

Austria

Bulgaria

Croatia

Portugal

Slovenia

Study description

Cholib® is a fixed combination tablet, composed of fenofibrate (145 mg) and simvastatin (20 mg or 40 mg) and indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL-C levels when LDL-C levels are adequately controlled with the corresponding dose of simvastatin monotherapy. As a part of the Risk Management Plan (RMP), a drug utilization study (DUS) using available data was planned to estimate the proportion of Cholib® initiators without prior simvastatin monotherapy was not feasible due to inadequate number of patients treated. An alternative approach in the form of a prescriber survey questionnaire in countries where found feasible (Austria, Portugal, Slovenia, Croatia, and Bulgaria) was proposed as per discussion with EMA. The primary objective is to estimate the proportion of first Cholib® prescriptions without prior prescription of simvastatin of the corresponding daily dose (off-label use). The Secondary objectives are to estimate the proportion of first prescriptions of fenofibrate/simvastatin free combination (FSFC) without prior prescription of simvastatin monotherapy of the corresponding daily dose in patients with mixed dyslipidaemia, to describe and categorize the indications for the fenofibrate/simvastatin initiation, differentiating between Cholib® and FSFC to describe demographic and clinical characteristics of patients receiving these drugs.This multi-national, cross-sectional and anonymous web-based survey will be conducted in both public and private settings about physician´s practice and a maximum of 4 recent consecutive anonymous prescriptions of

Cholib® and/or FSFC made during the preceding year. Results will be presented, overall and at country level per specialty.

Study status

Planned

Research institutions and networks

Institutions

IMS Health

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Institution

Contact details

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Study contact

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Primary lead investigator

Toussi Massoud

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/10/2016

Study start date
Planned: 01/01/2017

Data analysis start date
Planned: 01/03/2017

Date of final study report
Planned: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mylan

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

-To estimate the proportion of first Cholib® prescriptions without prior prescription of simvastatin of the corresponding daily dose ("off-label use").

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

FENOFIBRATE

SIMVASTATIN

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- 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

401

Study design details

Outcomes

-to estimate the proportion of first prescriptions of FSFC without prior prescription of simvastatin monotherapy of the corresponding daily dose in patients with mixed dyslipidemia,-to describe and categorize the indications for the fenofibrate/simvastatin initiation, differentiating between Cholib® and FSFC to describe demographic and clinical characteristics of patients receiving these drugs.

Data analysis plan

The statistical analysis will be conducted using the SAS® softwareV9.3 on Windows™ (SAS Institute, North Carolina, USA).Results will be presented, overall and at country level per specialty. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals of 95% will be calculated when relevant. Calculations will first be performed on raw data per specialty, and weighted according to the real proportion of targeted physicians in each

country to accurately reflect the population the survey seeks to measure. Possible selection bias will be assessed by comparing the distributions of available characteristics (e.g. region, age, gender, type of practice and specialty) between respondent and non-respondent physicians.

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

IMS will conduct the survey using HCPs lists from the MAH. In case of incomplete information for each HCP in the MAH lists, IMS will complete the information using its own data sources and lists (OneKey lists). The survey is a primary data collection conducted through a web questionnaire.

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