Drug utilisation study (DUS) on the use of Cholib® (fenofibrate and simvastatin fixed combination): a European multinational study using secondary health records databases

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Study Planned

Administrative details

EU PAS number

EUPAS9827

Study ID

15808

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Hungary

Study description

Statins have been shown to reduce total cholesterol and LDL-C levels. They are commonly used and recommended in patients with dyslipidaemia (Catapano et al. 2011).3 Fibrates are also used to lower total cholesterol and triglycerides (TG) levels. They are prescribed to patients intolerant to statins alone, or as second line of treatment in combination with statins.Combination of simvastatin and fenofibrate leads to additional improvement of lipid parameters compared with simvastatin monotherapy in patients with mixed dyslipidaemia who required a treatment targeting a broader lipoprotein spectrum (Grundy et al. 2005).11Cholib® is a fixed combination tablet, composed of fenofibrate (145 mg) and simvastatin (20mg or 40mg). It will be the first available registered drug combining both substances in one tablet.Cholib® is 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.Initiation of Cholib® treatment requires an adequate pre-treatement with simvastatin (at 20 or 40 mg) otherwise it is considered off-label use. This potential risk is part of the Risk Management Plan (RMP) and will be further investigated in this study conducted to estimate the proportion of patients who initiated Cholib® without prior simvastatin therapy.

Study status

Planned

Research institutions and networks

Institutions

IMS Health

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Institution

Contact details

Study institution contact

Toussi Massoud mtoussi@fr.imshealth.com

Study contact

mtoussi@fr.imshealth.com

Primary lead investigator

Toussi Massoud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/01/2015

Actual: 06/01/2015

Study start date

Planned: 01/06/2015

Date of final study report

Planned: 31/12/2017

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 list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

to estimate the proportion of patients with mixed dyslipidaemia, initiating Cholib® 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

Medical condition to be studied

Dyslipidaemia

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

323

Study design details

Data analysis plan

The statistical analysis will be conducted using SAS® software Version 9.3 for Windows ™ (SAS Institute, North Carolina, USA) and Excel.The statistical unit is the patient. Calculations will be performed on raw data without extrapolation.Continuous variables will be described by the number of valid cases, the number of missing values, mean, standard deviation, median, quartiles (Q1, Q3) and range.Categorical variables will be described as the total number and relative percentage per category.The number of missing data will be indicated, they will not be replaced and not be taken into account for the calculation of the percentages.Confidence intervals of 95% will be calculated for each item, when relevant.Prescribers' profile will be described per country: age, gender, specialty and region through LTD database.Summaries will be reported at country level. For each analysis period (pre- and post- launch periods) they will be categorized according to the speciality.

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 source(s), other

IMS Lifelink Longitudinal Prescription Database Hungary, IMS LifeLink EMR France

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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