Esmya ® Prescription Patterns in Europe: A Retrospective Drug Utilization Chart Review Study

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Study Ongoing

Administrative details

EU PAS number

EUPAS8533

Study ID

8534

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain

United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

inVentive Health

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Institution

Contact details

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Primary lead investigator

Erwin Göckeler-Leopold

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/05/2014

Actual: 06/06/2014

Study start date
Planned: 30/05/2014

Actual: 12/11/2014

Date of interim report, if expected
Planned: 11/02/2015

Date of final study report
Planned: 31/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PregLem SA

Study protocol

riskmgtsystem-pgl11020protocol.pdf(362.78 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The aim of this drug utilization study is to provide real-world data related to the current prescription utilization patterns of Esmya ®.Study objectives are as follows:• To document Esmya ® utilization patterns in real medical practice.• To characterize the patients who are prescribed Esmya ® in real medical practice.• To characterize the profile of prescribers of Esmya.

Study drug and medical condition

Name of medicine

ESMYA

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

1000

Study design details

Data analysis plan

• For the Interim Analysis, the Interim Study Group will include data from Cohort 1 (UK and Germany)• For the Final Analysis, the Final Study Group will include data from two cohorts, the Cohort 1 (UK and Germany) and the Cohort 2 (France, Italy and Spain). The number of patients in the Interim/Final Study Group and their associated characteristics will be described. The number of prescribers and their associated characteristics will also be described.Descriptive statistics will be used to summarize prescriber information and patient medical chart information. Summary statistics for continuous variables will include number of observations, mean, standard deviation, median, minimum, and maximum. Summary statistics for categorical data (dichotomous and polychotomous variables) will include counts and percentages. The 95% confidence intervals (95% CI) will be reported where appropriate. Country-specific analyses will be performed, where appropriate.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

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