Prasugrel Treatment Patterns in Outpatient Settings in Germany, the United Kingdom, and France (H7T-MC-B011)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20445

EU PAS number

EUPAS5911

Study ID

20445

DARWIN EU® study

No

Study countries

☐ France

☐ Germany

☐ United Kingdom

Study description

This study is a retrospective, nonintervention cohort study aimed at describing the treatment patterns of prasugrel in outpatient practices in Germany and France using the IMS Disease Analyzer and in the United Kingdom (UK) using the IMS Disease Analyzer and the Clinical Practice Research Datalink (CPRD), formerly known as General Practice Research Database (GPRD), starting from launch to 3 years postlaunch

Study status

Finalised

Research institutions and networks

Institutions

IMS Health

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2009

Actual: 23/03/2009

Study start date

Planned: 15/10/2009

Actual: 15/10/2009

Data analysis start date

Planned: 10/02/2013

Actual: 10/02/2013

Date of final study report

Planned: 09/04/2013

Actual: 09/04/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company and Daiichi Sankyo, Inc.

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objectives of the study were to provide descriptive statistics for the contraindication of TIA/stroke, maintenance dose, indication, patient characteristics, co-morbidities, co-prescriptions, and patterns of drug usage in outpatient practices in France, the UK, and Germany

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Effient

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Patients who had the first prescription records of prasugrel, also referred to as prasugrel initiators, in the IMS Disease Analyzer and CPRD after prasugrel

launch in France, the UK, and Germany. All prasugrel initiators in the IMS Disease Analyzer (France, the UK, and Germany) and CPRD were included.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Patients with acute coronary syndrome

Estimated number of subjects

4106

Study design details

Data analysis plan

The study population consisted of patients who had at least 1 prescription record of prasugrel in France and Germany using the IMS Disease Analyzer and in the UK using the IMS Disease Analyzer and the CPRD. The date of the first prasugrel prescription recorded in the databases was defined as the index date. The patients were followed from the index date until death, transfer out of the practice, or the end of the study, whichever came first. Descriptive statistics

(that is, mean SD, median, and quartile ranges for quantitative variables, and frequencies and percentages for qualitative variables) were provided for the contraindication of TIA/stroke, maintenance doses, body weight, patient demographic characteristics, co-morbidities, co-prescriptions, and patterns of drug usage in outpatient practices in respective countries.

Documents

Study results

B011 03 Synopsis_Part1.pdf(627.55 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

IMS France, IMS Germany, IMS United Kingdom

Data sources (types)

Disease registry

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

Unknown