EMA study on prescribing of ibuprofen in the French primary care setting

First published: 28/11/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS8075

Study ID

14400

DARWIN EU® study

No

Study countries

☐ France

Study description

The present study has been undertaken in the context of the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) Article 31 review to evaluate the cardiovascular risks with systemic

ibuprofen medicines. These risks concern high-dose ibuprofen (2,400 mg per day) taken regularly for long periods. Ibuprofen is usually taken at lower doses and for short periods of time. The primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults.Furthermore, the duration of the prescription will be calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods. This analysis includes all patients recorded in the France IMS database as having received a prescription of ibuprofen.The study period includes all data available in IMS France, from 1st January 1997 to 30th June 2014.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gianmario Candore

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2014

Actual: 01/11/2014

Study start date

Planned: 03/11/2014

Actual: 03/11/2014

Date of final study report

Planned: 14/11/2014

Actual: 14/11/2014

Sources of funding

- Other

More details on funding

Conducted using EMA resources

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 topic:

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 primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults.Furthermore, the duration of the prescription will be

calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01A) ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Population studied

Short description of the study population

Patients recorded in the France IMS database as having received a prescription of ibuprofen from 1st January 1997 to 30th June 2014.

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)

Estimated number of subjects

3889629

Study design details

Outcomes

The primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults. The duration of the prescription will be calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods.

Data analysis plan

This study is a descriptive analysis of EHR data from IMS Health. No sample size or statistical precision calculation is performed.

Documents

Study results

EMA_Ibuprofen IMS (FR) report.pdf(379.77 KB)

Study, other information

EMA_ibuprofen_DUS.pdf(289.75 KB)

Data management

Data sources

Data source(s), other

IMS Disease Analyser France database

Data sources (types)

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