Prescribing of zolpidem in the primary care setting in France, Germany and the UK during 2012. (Prescribing of zolpidem in IMS Germany/France/UK)

First published: 07/11/2013

Last updated: 19/07/2016

Study Finalised

Administrative details

EU PAS number

EUPAS5106

Study ID

14148

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

The present study aims to describe the extent and patterns of prescription of zolpidem in the primary care setting in three large EU countries in 2012 in line with the scope of an Article 31 referral. This has been done using the EMA's in-house IMS Health databases.The study includes patients from UK, Germany and France and for these patients the prevalence of zolpidem use in 2012 is stratified by gender and age. The prevalence of low strength (5 mg) and high strength (10 mg) prescribing and by different daily doses prescribed is also reported. In addition new users in 2011 has been characterised and the percentage starting at low/high strength and different daily doses is reported. These new users are followed up and the extent of use 3-6 months after the first prescription is studied.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Kristian Svendsen kristian.svendsen@ema.europa.eu

Study contact

kristian.svendsen@ema.europa.eu

Primary lead investigator

Kristian Svendsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/07/2013

Actual: 16/07/2013

Study start date

Planned: 02/09/2013

Actual: 02/09/2013

Data analysis start date

Planned: 09/09/2013

Actual: 09/09/2013

Date of interim report, if expected

Planned: 30/09/2013

Actual: 30/09/2013

Date of final study report

Planned: 25/10/2013

Actual: 25/10/2013

Sources of funding

- Other

More details on funding

There was no specific funding for the project which was 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 prevalence of zolpidem use in 2012 stratified by gender, age, strength and prescribed daily dose. In addition new users in 2011 has been characterised and the percentage and these new users are followed up after 3-6 months

Study drug and medical condition

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

ZOLPIDEM

Population studied

Short description of the study population

All patients receiving a prescription of zolpidem recorded in the IMS Disease Analyser

Age groups

Term newborn infants (0 – 27 days)

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

18000000

Study design details

Outcomes

Prevalence of prescribing in 2012-Stratified on age and gender-Stratified on prescribed strength-Stratified on the prescribed daily doseIncident use in 2011-stratified as above-Percentage having prescribed zolpidem 3-6 months after the initial prescription

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Data analysis plan

Descriptive study design. New user have been defined as patients with no prescription of the drug in question in the previous 12 months before first prescription in the calendar year in question (2011).Age grouping done to isolate elderly aged 65-79 and the very old aged 80 and older. The drug in question will be well captured in primary care databases (internal validity good) and the databases are considered representative for their respective countries (external validity good).

Documents

Study results

zolpidem report final with annex.pdf(833.29 KB)

Data management

Data sources

Data source(s)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

Data source(s), other

IMS Disease Analyzer United Kingdom

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