A Drug Utilisation Study of Domperidone in Europe Using Databases

First published: 11/11/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16062

Study ID

22405

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

The objective of the study is to investigate the effectiveness of risk minimisation measures and describe prescribing patterns of domperidone, including those pertaining to the off-label use of domperidone, in routine clinical practice in 5 European Union countries.Primary Objectives: To describe the prescribing patterns before and after the changes to the domperidone label and estimate and compare the overall proportion of domperidone prescriptions before and after implementation of the risk minimisation measures regarding the following measures:- Composite endpoint consisting of the following components: - Maximum daily dose, - Duration of use (>7 days) - Concomitant medications that prolong the QT-interval or are potent CYP3A4 inhibitors, - Prescribing to patients with contraindicated conditions, e.g., moderate or severe liver disease, underlying cardiac diseases, and - Prescribing for off-label indicationsSecondary Objectives: To estimate the overall proportion of domperidone prescriptions before and after implementation of the risk minimisation measures for domperidone for each of the components of the composite endpoint individually, the time trend of apparent indication, and days supplied (≤7 days vs. >7 days), and the age and sex of the people receiving prescriptions.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

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Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

Daniel Fife dfife@its.jnj.com

Study contact

dfife@its.jnj.com

Primary lead investigator

Oliveria Susan

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/10/2016

Study start date

Planned: 09/02/2017

Actual: 27/02/2017

Data analysis start date

Planned: 16/03/2017

Actual: 07/06/2017

Date of final study report
Planned: 21/08/2017

Actual: 15/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Domperidone Collaboration Study Group

Study protocol

DOMP - PASS Database Survey Protocol V2FINAL20JULY2016.pdf(457.01 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

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:

To describe the prescription patterns before and after the changes to the domperidone label and distribution of a DHPC and estimate and compare the overall proportion of domperidone prescriptions before and after implementation of the risk minimisation measures.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DOMPERIDONE

Population studied

Short description of the study population

All patients receiving domperidone in the outpatient setting during the pre-defined periods (pre- and post- implementation periods of the risk minimisation activity) in the selected European Union countries (France, Germany, United Kingdom, Belgium, and Spain).

Patients were included in the study cohort if they have at least 1 prescription for domperidone in the selected databases during the pre-defined periods, and have membership or have been registered with the practice and have available medical history for at least 180 days before the domperidone prescription.

Age groups

Preterm newborn infants (0 – 27 days)

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

110000

Study design details

Outcomes

Composite endpoint consisting of the following components:- maximum daily dose,- duration of use (> 7 days),- concomitant medications that prolong the QT-interval or are potent or strong CYP3A4 inhibitors,- prescribing to patients with contraindicated conditions- prescribing for off-label indications, To estimate the overall proportion of domperidone prescriptions before and after the implementation of the risk minimisation measures for domperidone for each of the components of the composite endpoint individually, the time trend of apparent indication, and days supplied (< 7 days vs > 7 days), and the age and sex of the people receiving prescriptions

Data analysis plan

Data analysis in the study will be descriptive. Continuous variables will be presented using appropriate descriptive statistics, such as mean, median, standard deviation and range. Categorical variables will be presented using percent and frequency tables. The rates and 95% CI of all study endpoints (i.e. risk minimisation indicators) will be calculated for the 2011-2015 period, using quarterly time blocks for the pre- and post- risk minimisation implementation periods. The rates will be calculated per 1000 domperidone-treated patients or as percentage of domperidone prescriptions, as appropriate.Paediatric data will be described separately from adult patients and rate of paediatric use will be calculated as fraction of overall domperidone utilisation. All data analysis will be done in SAS using the version that is current when the analyses are done.

Documents

Study results

DOMP-DUS-PASS database CSR_15DEC2017 FINAL_Synopsis.pdf(838.54 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

Unknown