A Post-Authorisation Safety Study (PASS) to Assess the Effectiveness of the Risk Minimisation Measures of Domperidone – Physician Survey

First published: 11/11/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16095

Study ID

19694

DARWIN EU® study

No

Study countries

Belgium

France

Germany

Spain

United Kingdom

Study description

Multi-national, non-interventional cross-sectional study to characterise prescriber's knowledge, understanding and extent of awareness regarding the new safety information for domperidone following the change in SmPC and the distribution of DHPC.Data will be collected through a physician survey to be administered in a group of prescribers, across 5 EU countries with varying prescription volumes: Belgium, France, Germany, Spain and United Kingdom.

Study status

Finalised

Research institutions and networks

Institutions

Adelphi Real World

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Taylor-Stokes Gavin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/10/2016

Study start date

Planned: 04/01/2017

Actual: 19/01/2017

Data analysis start date

Planned: 01/04/2017

Actual: 03/04/2017

Date of final study report

Planned: 30/06/2017

Actual: 27/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Domperidone DUS Collaboration Group

Study protocol

PASS Study_DUS_Physician Survey_Domperidone_JNJ-17296812-AAA_0005_EDMS-ERI-90221144_8.0.pdf (355.1 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:

Primary data collection

Main study objective:

Assess the awareness of the health care professionals and level of understanding and knowledge detailed in the risk minimisation activities (eg. DHCP) with respect to the safety and risk management of domperidone.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

DOMPERIDONE

Population studied

Short description of the study population

Prescribers, across 5 EU countries with varying prescription volumes: Belgium, France, Germany, Spain and United Kingdom.

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

0

Study design details

Outcomes

Characterise prescriber's knowledge, regarding the new safety information for domperidone following the change in SmPC, including:- Indications for domperidone prescribing- Length of treatment- Maximum daily dose- concomitant use of domperidone and other drugs known to prolong the QT-interval or potent CYP3A4 inhibitors- contraindicated conditions- treated population characteristics

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Data analysis plan

Descriptive statistics will be used for evaluation and comparison of prescriber knowledge and awareness as measured by the study survey. The study population will be described using demographic characteristics, such as age,

sex, specialty, clinical practice type, and country.Continuous variables will be presented using appropriate descriptive statistics, such as mean, median, standard deviation and range. Categorical variables will be described using frequencies.Further stratification by baseline variables may be performed and will be described in the statistical analysis plan.The primary analysis will present the rate of correct answers per question for all countries pooled together. An additional analysis will include the rates of correct answers by country. The proportion of physicians who potentially prescribe domperidone for unapproved indications will be described.

Documents

Study results

Domperidone PASS Study RRA-17004_CSR_Final 27JUN2017.pdf (606.64 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Physician Survey - the survey will be conducted using a multiple choice survey via the internet to address the most important safety information in the DHCP and potential off-label use

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