Post-Authorisation Safety Study (PASS) for Flupirtine – Effect of Risk Minimisation Measures in Germany

First published: 01/08/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14528

Study ID

23384

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This is a retrospective cohort study with pre-post design (before and after implementation of risk minimisation measures) using a longitudinal patient level Electronic Medical Records (EMR) database and a longitudinal patient level prescription database for Germany.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dorothea von Bredow

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/10/2014

Actual: 28/10/2014

Study start date
Planned: 01/07/2016

Actual: 01/07/2016

Data analysis start date
Actual: 15/07/2016

Date of final study report
Planned: 31/12/2016

Actual: 12/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hormosan Pharma GmbH

Study protocol

Lupin_PASS_ Flupirtine_Protocol Final Version 3 0_2015-09-24.pdf (473.17 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to evaluate the impact of the implementation of risk minimisation measures (RMMs) (DHPC and updated SmPC) on the prescription behaviour of physicians in Germany.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Cohort analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BG07) flupirtine

flupirtine

Medical condition to be studied

Pain

Population studied

Short description of the study population

All outpatients in Germany who have received flupirtine before and after implementation of risk minimisation measures identified from IMS® Disease Analyzer and IMS® LRx databases.

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

150000

Study design details

Outcomes

• indication for flupirtineDescription of proportion of patients with• pre-existing liver disease/alcohol abuse • pre-treatment with/ contraindications for NSAIDs and weak opioids• duration of treatment• single and repeated flupirtine prescriptions • concomittant use of hepatotoxic drugs• liver function test monitoring, The secondary objective of this study is to:• Compare the length of treatment or proportions observed for each of the objectives listed above in the

patients initiating flupirtine since implementation of RMMs to treatment length or proportions observed in the patients treated with flupirtine before the implementation of RMMs.

Data analysis plan

The data will be analysed separately by data source (IMS® Disease Analyzer and IMS® LRx).The statistical analysis will be done descriptively and performed separately by database, per physician panel and per observational period. All analyses will be stratified by incident and prevalent users. Missing values will be reported as missing and no imputation will be conducted. Descriptive tables will be made for all variables. Confidence intervals (95%) around estimates before and after the implementation minimization measures will be calculated. For comparison of patients initiating on flupirtine since the implementation of RMMs with patients treated with flupirtine before the implementation appropriate statistical tests will be used.

Documents

Study results

EMA_PASS_Flupirtine_Report abstract.pdf (47.75 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 source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Drug dispensing/prescription data

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