Evaluation of the Effectiveness of Risk Minimization Measures: Trimetazidine Drug Utilization Study in European Countries using databases – analysis for France, Hungary, Romania and Spain

First published: 02/06/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28831

EU PAS number

EUPAS9871

Study ID

28831

DARWIN EU® study

No

Study countries

France

Hungary

Romania

Spain

Study description

TMZ-containing medicinal products were indicated in EU for various cardiology, ophthalmology and otolaryngology indications. Otolaryngology and ophthalmology indications included:i. Ancillary symptomatic treatment of vertigo and tinnitus andii. Ancillary treatment of visual acuity decrease and visual field disturbances due to vascular reasonsOn 22 April 2011, France had requested the Committee for Medicinal Products for Human Use (CHMP) to give its opinion under Article 31 of Directive 2001/83/EC on whether the marketing authorization for TMZ-containing medicinal products will be maintained, varied, suspended or withdrawn.The review conducted by the CHMP concluded that the evidence of the efficacy and safety in the ophthalmology and otolaryngology indications, initially suggested by the studies on the basis of multiple assessments was considered weak due to the methodology applied to the investigation and was no longer recommended since September 2012 (3).Potential prescribers were informed of this change in the indication of TMZ through “Direct Healthcare Professional Communications” (DHPCs) and other appropriate notifications. The drug utilization study presented here is designed to evaluate the effectiveness of these risk minimization measures (RMM) on the use of TMZ in targeted countries based on information from prescription databases. In a parallel protocol, a survey will be conducted to provide information on the knowledge, attitude and behaviour of the physicians in the targeted countries about the content of the DHPC and the updated SMPC are evaluated.

Study status

Finalised

Research institution and networks

Institutions

Real World Evidence Solutions, IMS Health

France

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Institution | Other

NA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/01/2015

Actual: 08/01/2015

Study start date
Planned: 01/06/2015

Actual: 01/06/2015

Date of final study report
Planned: 30/09/2015

Actual: 16/09/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Consoritum headed by Lupin Pharma

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to Assess, per country, the proportion of prescriptions of TMZ for ophthalmological or ENT diagnoses (within the scope of its past indications) among the total prescriptions of TMZ after the restriction of its indications.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

TRIMETAZIDINE

TRIMETAZIDINE DIHYDROCHLORIDE

Medical condition to be studied

Angina pectoris

Population studied

Short description of the study population

ENT specialists, ophthalmologists, cardiologist and GPs/other who has prescribed Trimetazidine.

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

1500

Study design details

Data analysis plan

The statistical analysis will be conducted using SAS® software Version 9.3 for Windows™ (SAS Institute, North Carolina, USA).The analysis will include descriptive statistics. Interrupted time series (ITS) analysis will be conducted if the conditions are met.The number of missing data will be indicated. Missing

data will not be replaced by imputation methods. The statistical unit will be the prescription (for extractions from PI) or the dispensed prescription (for extractions from NDI and NPA database).Prescribers' profile will be described per country: age, gender, speciality and region. Summaries will be reported at country level and by period (reference period and assessment period) categorized according to the speciality.

Documents

Study results

Abstract Trimetazidine PASS DUS_Redacted.pdf(88.21 KB)

Data management

Data sources

Data source(s), other

IMS health prescribing insights France, IMS health prescribing insights Spain, National diagnostic index Romania, National prescribing audit Hungary

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

No