Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of Trimetazidine in Bulgaria, Czech Republic, Estonia, France, Hungary, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Spain

First published: 25/11/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8044

Study ID

18842

DARWIN EU® study

No

Study countries

Bulgaria
Czechia
Estonia
France
Hungary
Latvia
Lithuania
Poland
Portugal
Romania
Slovakia
Spain

Study description

Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of Trimetazidine in Bulgaria, Czech Republic, Estonia, France, Hungary, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Spain

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

Toussi Massoud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/11/2014

Actual: 05/11/2014

Study start date

Planned: 20/11/2014

Actual: 24/11/2014

Data analysis start date
Planned: 02/01/2015

Date of final study report
Planned: 31/03/2015

Actual: 28/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Consortium led by Lupin

Study protocol

Trimetazidine Lupin Survey Protocol_update 24 Nov 2014, V3.0, clean.pdf (1.09 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primary objective: • to evaluate the proportion of targeted physicians who received, understood and agreed to implement the updated information about TMZ provided in the DHPC

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

TRIMETAZIDINE

Population studied

Short description of the study population

Physicians who were prescribers, or potential prescribers, of TRIMETAZIDINE; and specialists of any of those targeted for the DHPC: ENT-specialists, ophthalmologists, cardiologists, others (GPs, internists, geriatricians).

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

5.000

Study design details

Data analysis plan

All analysis will be descriptive in nature and no statistical comparison will be done in this study. Results will be presented overall, by country and per specialty. Quantitative data will be summarized descriptively using n, mean, median, standard deviation, minimum and maximum. Categorical data will be summarized using frequency and percentage. 95% confidence interval (Wald’s) may be constructed around the percentage values for some variables. Some of

the variables may also be summarized by country. All variables will be analyzed in total and separately for ophthalmologists, ENT specialists, cardiologists and others based on the information provided.In a first step, calculations will be performed on raw data. In a second step, the results will be weighted according to the real proportion of physicians in each country

Documents

Study results

Trimetazidine Lupin Abstract_final Survey Report_20160120_Version 2 0-Clean.pdf (27.63 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Case report forms

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