Drug utilisation study, in five European countries, using cross sectional analysis, to assess the extent of prescriptions of trimetazidine for its withdrawn ophthalmological and ENT indications among general practitioners, ophthalmologists and ENT specialists

First published: 02/03/2017

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18049

Study ID

18050

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Greece
- [ ] Poland
- [ ] Romania
- [ ] Spain

Study description

The aim of the study was to verify the compliance of prescribers regarding the restricted indication of trimetazidine after marketing authorisation changes in 2012. The primary objective was to assess, per country, the proportion of prescriptions of trimetazidine for ophthalmological or ENT diagnoses (within the scope of its past indications) among the total prescriptions of trimetazidine after the restriction of its indications.

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

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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

Actual: 27/09/2012

Study start date

Planned: 01/12/2012

Actual: 01/12/2012

Data analysis start date

Planned: 01/07/2014

Actual: 01/07/2014

Date of final study report

Planned: 30/09/2014

Actual: 10/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Les Laboratoires Servier

Study protocol

DUS protocol_Final version_2014-06-04.pdf(2.14 MB)

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Assess, per country, the proportion of prescriptions of TMZ for ophthalmological and/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

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C01EB15) trimetazidine

trimetazidine

Medical condition to be studied

Angina pectoris

Population studied

Short description of the study population

Trimetazidine prescribed patients who consulted general practitioners, ophthalmologists and ENT specialists during the study periods in the five targeted countries.

Age groups

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

1920

Study design details

Outcomes

The primary end point was the proportion of TMZ prescriptions for ophthalmological and/or ENT diagnoses (within the scope of its past indications) among all TMZ prescriptions in the targeted prescribers of each country. Assess the extent of TMZ prescriptions: for ophthalmo or ENT diagnoses before and after the restriction of its indications by specialty (GPs, ophthalmo, ENT specialists), with regards to specialists’ characteristics, after the restriction of

its indications by GPs in the cardiovascular indication and by GPs (FR, ES) for angina pectoris without other concomitant prescriptions for angina pectoris.

Data analysis plan

The statistical analysis was conducted using SAS® software Version 9.2 for Windows ™ (SAS Institute, North Carolina, USA).Continuous variables were described by the number of valid cases, the number of missing values, mean, standard deviation, median, Q1, Q3 and range.Categorical variables were described as the total number and relative percentage per category. The number of missing data was indicated and missing data was not taken into account for the calculation of the percentages. Confidence intervals of 95% were calculated for each item, when relevant. The statistical unit was the prescription (for extractions from PI database) or the dispensed prescription (for extractions from NDI database). Calculations were performed on raw data. Prescribers' profile was described per country: age, gender and region. Summaries were reported at country level and by period (Reference period and assessment period) categorized according to the speciality.

Documents

Study results

DUS Abstract 2015-12-10.pdf(184.89 KB)

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

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