Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey and Drug Utilisation Study among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of valproate in France, Germany, Spain, Sweden and United Kingdom

First published: 23/10/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11379

Study ID

23396

DARWIN EU® study

No

Study countries

France

Germany

Spain

Sweden

United Kingdom

Study description

Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey and Drug Utilisation Study among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of valproate in France, Germany, Spain, Sweden and United Kingdom

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: 30/11/2015

Actual: 01/06/2016

Study start date

Planned: 31/03/2015

Actual: 31/08/2016

Date of final study report

Planned: 30/11/2016

Actual: 09/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

A consortium of MAHs

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 type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Survey

Data collection methods:

Primary data collection

Main study objective:

The objective of the survey is to measure the effectiveness of the DHPC and educational material (EM), implemented as part of risk minimisation measures, by ascertaining the proportion of targeted physicians who understood and implemented the latest prescribing conditions and safety information about valproate provided in the DHPC and EM.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

SODIUM VALPROATE

VALPROATE SEMISODIUM

VALPROIC ACID

VALPROMIDE

Medical condition to be studied

Epilepsy

Bipolar disorder

Migraine

Pregnancy

Population studied

Short description of the study population

Prescribers of valproate in settings of 5 European countries (France, Germany, Spain, Sweden, UK).

Age groups

- 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)

Special population of interest

Pregnant women

Estimated number of subjects

1067

Study design details

Data analysis plan

The statistical analysis will be conducted using the SAS® softwareV9.4on Windows™ (SAS Institute, North Carolina, USA).The statistical results of the five

countries will be presented in the same report, overall, per country and per physician’s specialty group.All the analysis will be descriptive in nature and no statistical comparison will be done in this study.Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, and median, Q1, Q3, minimum and maximum.Categorical variables will be described as the total number and relative percentage per category. These will be the percentage per category.Free text answers to open-ended questions will be categorised by theme, listed according to the frequency.Confidence intervals of 95% will be evaluated, when relevant.The proportions of correct and appropriate answers to selected questions asked in the questionnaire will be expressed among physicians.

Documents

Study results

valproate-PASS survey report abstract v1 2018-01-16.pdf (99.08 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 and prescription survey

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