A Joint Drug Utilisation Study (DUS) of valproate and related substances, in Europe, using databases

First published: 07/05/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9678

Study ID

32834

DARWIN EU® study

No

Study countries

France

Germany

Spain

Sweden

United Kingdom

Study description

The aim of this study is to describe the prescribing practices before and after the dissemination of risk minimisation measures (i.e. educational materials and Dear Healthcare Professional Communication) and to assess the effectiveness of these measures in females through measure of prevalence of prior medication used before valproate.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Toussi Massoud mtoussi@fr.imshealth.com

Study contact

mtoussi@fr.imshealth.com

Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2015

Actual: 01/03/2016

Study start date

Planned: 31/03/2016

Actual: 31/03/2016

Data analysis start date

Planned: 15/06/2016

Actual: 15/06/2016

Date of interim report, if expected

Planned: 31/01/2017

Actual: 23/12/2016

Date of final study report

Planned: 31/08/2019

Actual: 28/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Consoritum of 22 MAH, led by Sanofi Aventis

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:

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 study objective is to describe prescribing patterns in the outpatient setting during the pre- and post-implementation periods, with the description of:- Demographic characteristics of female users of valproate in oral form.- Valproate treatment characteristics, medical history prior to valproate initiation, prior and concomitant medications with valproate related to the indication

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SODIUM VALPROATE

VALPROATE SEMISODIUM

VALPROMIDE

VALPROIC ACID

Medical condition to be studied

Pregnancy

Contraception

Population studied

Short description of the study population

All female patients receiving valproate prescriptions during the predefined pre- and post- implementation periods in the selected databases of target countries.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

30.000

Study design details

Outcomes

The assessment of the effectiveness of the risk minimisation measures in the outpatient setting will take into account the number of patients with at least one medication used prior the valproate initiation and related to the valproate indication (epilepsy, bipolar troubles, migraine headaches and other) within 12 months before the index date. To describe the prescribing practices of valproate before and after the dissemination of risk minimisation measures in the outpatient setting, the following parameters will be considered:- Demographic characteristics of initiated valproate users:o Age of included patients- Medical history related to valproate initiation up to 2 years before the index date (epilepsy, bipolar troubles, ...

Data analysis plan

The main analysis will compare the prescribing patterns of valproate during the pre- and post- implementation periods in females and in the outpatient settings, to meet the primary study objective. The analysis will be descriptive in nature. Descriptive statistics will be provided for the patients, treatments and diagnosis characteristics. Categorical variables will be presented as counts (n), proportions (%) and confidence interval (CI) when relevant . Continuous variables will be presented as means with standard deviation (SD) and as medians with inter quartile range (IQR) as appropriate.Results will be displayed by period before and after the implementation of RMMs, and by country. The main periods in the pre- and post-implementation periods will be considered as primary analysis and the transition periods will be considered for sensitivity analysis.

Documents

Study results

Abstract_DUS_Valproate_forEU_PAS_register_fin_clean.pdf (96.2 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)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

HTI – Hospital Treatment Insights

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

Data sources (types)

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

No