Trends in prescriptions of valproate and valpromide for bipolar disorder in IMS France and IMS Germany between 2010 and June 2016 and in UK THIN between 1999 and 2015

First published: 18/05/2017

Last updated: 15/12/2021

Study Finalised

Administrative details

EU PAS number

EUPAS19162

Study ID

44731

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

This study will provide drug utilisation data on valproate prescribing among the general population using data from France, Germany and the UK.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Daniel Morales Daniel.Morales@ema.europa.eu

Study contact

Daniel.Morales@ema.europa.eu

Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/01/2017

Actual: 03/01/2017

Study start date
Planned: 03/01/2017

Actual: 03/01/2017

Data analysis start date
Planned: 03/01/2017

Actual: 09/01/2017

Date of final study report
Planned: 31/08/2017

Actual: 06/06/2017

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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:

Measure prevalence and prescribing trends in valproate prescribing overall and in people with certain indications in the general population.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AG01) valproic acid

valproic acid

Medical condition to be studied

Bipolar disorder

Epilepsy

Migraine

Population studied

Short description of the study population

All patients with a consultation date between 1 January 2010 and 30 June 2016 were identified.

Population denominators used for the analysis of valproate prescribing trends in THIN are defined as follows:

a) All patients with bipolar disorder meeting cohort entry and exit criteria described above.

b) All patients in the THIN database.

c) All patients with a Read code for epilepsy recorded in each calendar year in THIN.

d) All patients with a Read code for migraine recorded in each calendar year in THIN.

Different cohort denominators were used for epilepsy and migraine to reflect active management of patients as opposed to bipolar disorder which is a more pervasive chronic illness. In this regard, it was noted that inclusion of people simply with a past history of epilepsy and migraine lead to an underestimation of the prevalence of valproate prescribing over time (due to the accrual of non-

active patients).

Age groups

- 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

Other

Special population of interest, other

Population with Bipolar disorder, Epilepsy and Migraine

Estimated number of subjects

100.000

Study design details

Outcomes

Prevalence of valproate prescribing overall and in people with certain indications (e.g. bipolar disorder, epilepsy, migraine) in the general population.

Data analysis plan

Simple descriptive analysis with counts and percentages. Annual and quarterly time trends in valproate prescribing.

Documents

Study results

EMA Valproate_prescribing_REPORT.pdf (1.19 MB)

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)

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

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