A Drug Utilisation Study extension (DUS ext.) of valproate and related substances, in Europe, using databases (VALNAC09343)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48966

EU PAS number

EUPAS34519

Study ID

48966

DARWIN EU® study

No

Study countries

☐ France

☐ Germany
☐ Netherlands
☐ Spain
☐ Sweden
☐ United Kingdom

Study description

The aim of this study is to describe the prescribing practices before and after the dissemination of the new risk minimization measures (RMMs) (planned over Q2 2018 – Q4 2018, depending on approval by National Competent Authorities) in Europe and to assess the effectiveness of these measures.

Primary objectives:

• To describe and compare the prescribing practices in women of child bearing potential (WCBP) receiving valproate during the pre- and/or post-implementation period with respect to elements of the PPP (where available in each of the data sources) separately:

o Use of contraceptives without interruption during treatment o Laboratory pregnancy tests before treatment o Treatment reviews by a specialist at least once per year (using a proxy of consultation by a specialist as a marker for treatment review),

o Specialty of prescribing physician at initiation.

• To describe and compare proportion of patients for which all elements of the PPP measurable with this DUS are fulfilled, during the pre- and/or post-implementation period,

• To describe and compare the incidence of valproate exposed pregnancies, and characteristics of exposed pregnancies during the pre and post implementation period.

This is a non-interventional longitudinal retrospective cohort study of WCBP

exposed to valproate, conducted with secondary data obtained from electronic medical records or administrative healthcare databases in different European countries (i.e. France, Germany, the Netherlands, Spain, Sweden, and the UK). The study population will include all WCBP receiving valproate prescriptions during the pre-defined periods (pre- and post-implementation periods). The analyses will be mainly descriptive and will be conducted by country, database, and study time periods.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mickael Arnaud

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/10/2018

Study start date
Planned: 01/08/2020

Date of final study report
Planned: 28/02/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

A Consortium of Marketing Authorization Holders for valproate and related substances

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)

Regulatory procedure number

EMEA/H/A-31/1454

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is mentioned in study summary due to lack of space here. The aim of this study is to describe the prescribing practices before and after the dissemination of the new risk minimization measures (RMMs) (planned over Q2 2018 - Q4 2018, depending on approval by National Competent Authorities) in Europe and to assess the effectiveness of these measures.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VALPROIC ACID

VALPROMIDE

Anatomical Therapeutic Chemical (ATC) code

(N03AG01) valproic acid

valproic acid

(N03AG02) valpromide

valpromide

Medical condition to be studied

Epilepsy

Bipolar disorder

Pregnancy

Population studied

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

2304

Study design details

Data analysis plan

Given the study objectives the analyses will be mainly descriptive and will be conducted by country, database, and study time periods (both pre-implementation periods and post-implementation period). Categorical variables will be presented as counts (n), proportions (%) with confidence interval (CI) where relevant. Continuous variables will be presented as means with standard deviation (SD) and as medians with interquartile range (IQR), where appropriate. The main analyses will compare the prescribing practices in WCBP receiving valproate during the pre- and post-implementation periods with respect to key elements of the PPP and will compare the incidence of valproate exposed pregnancies, and characteristics of exposed pregnancies during the same periods to meet the primary study objective.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

German Pharmacoepidemiological Research Database

Système National des Données de Santé (French national health system main database)

Data source(s), other

Swedish national registries, Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Exposure registry

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