Utilisation of antiepileptic medicines in girls and women of childbearing potential - a study in three European countries

First published: 19/05/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19129

Study ID

26083

DARWIN EU® study

No

Study countries

France

Italy

United Kingdom

Study description

The use of certain antiepileptic drugs (AEDs) is known to increase the risk of both physical and neurodevelopmental abnormalities in the foetus and child. The European Medicines Agency recently carried out a review of the evidence relating to the use of the AED sodium valproate during pregnancy. Following this review, the guidelines for prescribing sodium valproate to women of childbearing age were changed in January 2015.This study will use electronic healthcare data from databases in the United Kingdom, France and Italy (Tuscany and Emilia Romagna). The study will calculate the prevalence of AED prescribing in all females of childbearing age and in females during pregnancy, stratified by calendar year, age at prescription and indication for prescribing. It will also look at the incidence of prescribing of each of the different AEDs among new users stratified by calendar year, age at prescription and indication for prescribing and evaluate the extent to which women switch AED products, particularly in relation to pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacy & Pharmacology, University of Bath

United Kingdom

First published: 30/04/2010

Last updated: 08/04/2019

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

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United Kingdom

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Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

First published: 31/03/2022

Last updated: 01/07/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Centre for Environmental and Preventive Medicine, Queen Mary University of London United

Kingdom, Drug Policy Service, Emilia Romagna Region Health Authority Italy

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Charlton Rachel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/12/2016

Actual: 16/12/2016

Study start date

Planned: 09/05/2017

Actual: 24/05/2017

Data analysis start date

Planned: 09/09/2017

Actual: 09/09/2017

Date of interim report, if expected
Actual: 04/05/2018

Date of final study report
Planned: 09/05/2018

Actual: 07/06/2018

Sources of funding

- EMA

Study protocol

EMA EUROmediSAFE AED PROTOCOL_EU PAS Register.pdf (875.37 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To characterise the prescription patterns of antiepileptic drugs (AEDs) in girls and women of childbearing potential between January 2007 and December 2016, using electronic healthcare data from the United Kingdom (UK), France and Italy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03A) ANTIEPILEPTICS

ANTIEPILEPTICS

Population studied

Short description of the study population

All females aged between 10 and 50 years during the study period in each of the databases. In order to be eligible, females must have contributed a minimum of 365 days to the database. The cohort entry date will be the latest of the date when they joined the database + 365 days, the date of their 10th birthday or 1-Jan-2007. The cohort exit date will be the earliest of the date they left the database, the date of their 51st birthday or 31-Dec-2016.

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

5.439.534

Study design details

Data analysis plan

The prevalence of AED prescribing (overall and for specific AEDs) will be calculated per 1,000 female population with 95% confidence intervals (CI95). This will be calculated stratified by calendar year, age at prescription and indication for prescribing. The incidence of AED prescribing (new users) (overall and for specific AEDs) will be calculated per 10,000 person-years with CI95 stratified by calendar year, age at prescription and indication for prescribingThe prevalence of AED prescribing will be calculated during the 6 months before

pregnancy (broken into 3-month time periods) and during each of the pregnancy trimesters. The prevalence of prescribing will be calculated stratified by pregnancy outcome, calendar year at pregnancy start and indication for prescribingThe percentage of women prescribed AEDs who initiate a switch in treatment will be calculated (overall and for each specific AED) stratified by calendar year, age at first switch and indication for prescribing.

Documents

Study results

MEANING AND IMPLICATIONS OF THE STUDY RESULTS.pdf (424.03 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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

ENCePP Declaration of interests_19129.pdf (158.6 KB)

Composition of steering group and observers

ENCePP Composition of Steering Group and Observers_EUROmediSAFE 2017.pdf (170.29 KB)

Signed code of conduct

2017-0044_Declaration of compliance with CoC-signed_EUPAS19129.pdf

(182.96 KB)

Signed code of conduct checklist

2017-0044_ENCePP CoC checklist-signed_EUPAS19129.pdf (173.52 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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

Unknown