

# 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

### PURI

<https://redirect.ema.europa.eu/resource/26083>

### EU PAS number

EUPAS19129

### Study ID

26083

### DARWIN EU® study

No

### Study countries

☐ France

☐ Italy

☐ United Kingdom

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### **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.

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### **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**

Educational Institution

Hospital/Clinic/Other health care facility

ENCEPP partner

## Pharmacy & Pharmacology, University of Bath

☐ United Kingdom

**First published:** 30/04/2010

**Last updated:** 08/04/2019

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

ENCEPP partner

## 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

Charlton Rachel

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

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### Study start date

Planned: 09/05/2017

Actual: 24/05/2017

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**Data analysis start date**

Planned: 09/09/2017

Actual: 09/09/2017

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**Date of interim report, if expected**

Actual: 04/05/2018

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**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

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

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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.

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## **Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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## **Special population of interest**

Pregnant women

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## **Estimated number of subjects**

5439534

# 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 prescribing. The 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 prescribing. The 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)

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## Data management

## ENCePP Seal

**This study has been awarded the ENCePP seal**



### Conflicts of interest of investigators

[ENCePP Declaration of interests\\_19129.pdf](#)(158.6 KB)

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### Composition of steering group and observers

[ENCePP Composition of Steering Group and Observers\\_EUROmediSAFE 2017.pdf](#)(170.29 KB)

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### Signed code of conduct

[2017-0044\\_Declaration of compliance with CoC-signed\\_EUPAS19129.pdf](#)(182.96 KB)

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**Signed code of conduct checklist**

[2017-0044\\_ENCePP CoC checklist-signed\\_EUPAS19129.pdf](#)(173.52 KB)

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## Data sources

**Data source(s)**

Clinical Practice Research Datalink

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

Unknown