

Tender for Competition no.6: Methods and data sources for determining long-term effects of drug exposure during pregnancy, with application to antiepileptic medicines. EUROmediSAFE Consortium

First published: 10/10/2017

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Study

Finalised

Administrative details

EU PAS number

EUPAS21171

Study ID

27936

DARWIN EU® study

No

Study countries

 United Kingdom

Study description

This study will seek to compile an inventory of available data sources in all 28 European Union Member States for potential use when evaluating the long-term risks of for children associated with in-utero exposure.

Study status

Finalised

Research institutions and networks

Institutions

Queen Mary University of London

Contact details

Study institution contact

Joan Morris j.k.morris@qmul.ac.uk

Study contact

j.k.morris@qmul.ac.uk

Primary lead investigator

Joan Morris

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/12/2016

Study start date

Planned: 18/04/2016

Actual: 23/05/2017

Data analysis start date

Planned: 09/11/2017

Actual: 09/11/2017

Date of interim report, if expected

Actual: 04/05/2018

Date of final study report

Planned: 09/05/2018

Actual: 06/07/2018

Sources of funding

- EMA

Study protocol

[Draft protocol v20_afterPRAC_clean.pdf](#) (933.67 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:

Disease /health condition

Human medicinal product

Other

Study topic, other:

Identification of sources of data and databases

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If 'other', further details on the scope of the study

Identify sources of data

Data collection methods:

Secondary use of data

Main study objective:

To identify potential sources of population-based cohort data for future studies

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Identification of sources of data and databases

Population studied

Short description of the study population

N/A

Age groups

- Preterm newborn infants (0 - 27 days)
 - Term newborn infants (0 - 27 days)
 - Infants and toddlers (28 days - 23 months)
 - Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
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Special population of interest

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

Report: the inventory of data sources will consist of three parts, namely an inventory of data sources for in utero-exposure, an inventory of data sources for evaluating the long-term risks for children and (if possible) a preliminary investigation into the regulations governing the use of social media in the 28 EU Member States, To provide information for a study protocol to estimate the association between exposure to antiepileptic medicines in-utero and neurodevelopmental disorders in the offspring

Data analysis plan

Tabulation of number of data sources per country and description of available databases

Documents

Study results

[EUROmediSAFE Inventory_Finalv2_2018_07_06.pdf](#) (1.78 MB)

Study publications

[Inventory may be downloaded from website](#)

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 sources (types)

Other

Data sources (types), other

We are looking for sources of data using personal contacts, the internet and literature reviews

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