Safety of psychotropic medication in pregnancy: A pharmacovigilance study of international safety data in the World Health Organization global individual case safety report (ICSR) database ‘VigiBase’.

First published: 08/11/2022

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS49262

Study ID

49263

DARWIN EU® study

No

Study countries

Greece

Study description

The present protocol aims to use disproportionality analysis to identify safety signals of individual psychotropic drug use and pregnancy related adverse events using VigiBase, the World Health Organization global individual case safety report (ICSR) database.

Study status

Planned

Research institutions and networks

Institutions

CLINICAL RESEARCH UNIT, SCHOOL OF MEDICINE, PAPAGEORGIOU GENERAL HOSPITAL, ARISTOTLE UNIVERSITY OF THESSALONIKI (CRU-AUSoM)

Greece

First published: 26/02/2024

Last updated: 13/05/2025

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Department of Clinical Pharmacology & Clinical Research Unit

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dainora Cepaityte

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/05/2021

Study start date

Planned: 10/10/2022

Data analysis start date

Planned: 02/01/2023

Date of final study report

Planned: 31/12/2023

Sources of funding

- Other

More details on funding

Study not funded

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

Identify safety signals of individual psychotropic drug use and pregnancy related adverse events using VigiBase, the World Health Organization global individual case safety report (ICSR) database.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case/non-case design

Study drug and medical condition

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

LITHIUM

VALPROIC ACID

LAMOTRIGINE

CARBAMAZEPINE

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

(N05B) ANXIOLYTICS

ANXIOLYTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N06BA) Centrally acting sympathomimetics

Centrally acting sympathomimetics

Medical condition to be studied

Foetal disorder

Neonatal disorder

Pregnancy

Stillbirth

Abortion spontaneous

Congenital anomaly

Foetal malformation

Additional medical condition(s)

Specifically, Standardized MedDRA queries:,“Congenital, familial and genetic disorders”, “Foetal disorders”, “Lactation related topics (incl neonatal exposure through breast milk)”, “Neonatal disorders”, “Normal pregnancy conditions and outcomes”, “Pregnancy, labour and delivery complications and risk factors (abortions and stillbirth)”, “Termination of pregnancy and risk of abortion”.

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

3000000

Study design details

Outcomes

Risk of reporting a pregnancy related outcome.

Data analysis plan

Data will be extracted from VigiBasa, a case/non-case design will be used for disproportionality analysis to calculated reporting odds ratios (RORs) with their 95% confidence interval (CI). The measure of disproportionality in this study is the reporting odds ratio (ROR) which corresponds to the ratio of reporting odds between groups exposed and not exposed to each drug of interest.

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)

Spontaneous reports of suspected adverse drug reactions

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