Demonstrating solutions for studying intermittent medication exposures in diseases with episodic manifestations during pregnancy: application to medication for migraine in pregnancy

First published: 04/10/2021

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS43409

Study ID

43410

DARWIN EU® study

No

Study countries

- [ ] Finland
- [ ] France

- [ ] Germany
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

This study will be conducted within the ConcePTION project of the Innovative Medicines Initiative under grant agreement No 821520. This study is based on electronic health care registry data from 9 health care data bases in 7 European countries between 2005 and 2019/most recent data available. The study is divided into a medication utilisation part, and a medication safety part. The objective are as follows: Medication utilisation study: to describe drug utilization patterns in women with migraine over the course of pregnancy, focusing especially on intermittent migraine medication use, using triptans as the motivating example. Medication utilisation before, during and after pregnancy will be reviewed and compared across data sources. Medication safety study: To study the association between prenatal exposure to triptans and adverse maternal and pregnancy outcomes. The potential impact of exposure misclassification on exposure-outcome associations will be assessed under a range of scenarios. Results from across data sources will be combined using meta-analytic techniques.

Study status

Planned

Research institutions and networks

Institutions

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Finnish Institute for Health and Welfare (THL)

Finland

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo

Norway

First published: 19/10/2016

Last updated: 06/11/2025

Institution | Educational Institution | ENCePP partner

Emilia-Romagna Health and Social Agency (ASSR Emilia-Romagna)

Italy

First published: 23/04/2010

Last updated: 18/12/2017

Institution | Outdated | Laboratory/Research/Testing facility | ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 31/10/2025

Institution

Swansea University Scotland, FISABIO, Área de Investigación en Enfermedades Raras Spain, Centre Hospitalier Universitaire France, Finnish Institute for Health and Welfare, Information Services Department Finland

Networks

ConcepTION

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hedvig Nordeng

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2019

Study start date
Planned: 08/05/2021

Date of final study report
Planned: 15/03/2023

Sources of funding

- EU institutional research programme
- Pharmaceutical company and other private sector

More details on funding

EFPIA, Innovative Medicines Initiative (IMI), grant No 821520

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

Disease epidemiology

Drug utilisation

Main study objective:

To study the association between prenatal exposure to triptans/migraine medications and adverse maternal and pregnancy outcomes. The potential impact of exposure misclassification on exposure-outcome associations will be assessed under a range of scenarios. Further, to describe drug utilization patterns in women with migraine, and identify event finding algorithms for migraine and maternal events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02CC) Selective serotonin (5HT1) agonists

Selective serotonin (5HT1) agonists

Medical condition to be studied

Migraine

Vomiting

Gestational diabetes

Maternal hypertension affecting foetus

Premature baby

Low birth weight baby

Small for dates baby

Live birth

Congenital anomaly

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

5000000

Study design details

Outcomes

Major congenital anomalies in offspring, maternal preeclampsia and gestational diabetes mellitus, - non-live birth (y/n) - preterm birth (y/n), GA (cont. in days) - low birth weight (y/n), BW (cont. in gram, z-scores) - small for gestational age/ intrauterine growth restriction

Data analysis plan

We will estimates prevalence of migraine medication use in the drug utilisation part. In the safety part of the study, risk ratios/hazard ratios/mean differences of the various outcomes by exposure status are estimated using regression models. We will account for confounding using methods within the causal inference framework (eg, marginal structural models). Absolute risk difference and population attributable fractions will also be computed.

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 source(s)

Clinical Practice Research Datalink

EFEMERIS

German Pharmacoepidemiological Research Database

ARS Toscana

Data source(s), other

CPRD, Emilia Romagna GPs drug prescription, EFEMERIS, Drugs and Pregnancy Finland, GePaRD, ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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