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

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# 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			
<b>Last updated:</b> 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			
<b>Last updated:</b> 08/11/2016			
Institution Outdated Educational Institution ENCePP partner			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Institution Outdated Laboratory/Research/Testing facility ENCePP partner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)

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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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### Contact details

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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