A Population-based Cohort Study of Pregabalin to Characterize Pregnancy Outcomes

First published: 27/12/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27339

Study ID

36881

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Norway
- [ ] Sweden

Study description

The study objectives are to describe the use of pregabalin exposure in pregnancy and to estimate the risk of major congenital malformations, birth outcomes other than congenital malformations and neurodevelopmental outcomes with the use of pregabalin.

Study status

Finalised

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Global Database Studies, IQVIA

- [ ] Czechia
- [ ] Finland
- [ ] Germany
- [ ] Slovakia
- [ ] Spain

First published: 17/01/2011

Last updated: 31/07/2024

Institution | Other | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

- [ ] Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

University of Bergen Norway, Department of clinical epidemiology, Centre for Pharmacoepidemiology, EPID Research

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vera Ehrenstein

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2018

Actual: 15/06/2018

Study start date

Planned: 30/12/2018

Actual: 30/12/2018

Date of final study report

Planned: 30/11/2019

Actual: 01/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

Pregabalin Pregnancy Outcomes Study Protocol Final 23NOV 2018 CLEAN.pdf
(859.6 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

A0081359

Methodological aspects

Study type

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The study objectives are to describe the use of pregabalin exposure in pregnancy and to estimate the risk of major congenital malformations, birth outcomes other than congenital malformations and neurodevelopmental outcomes with the use of pregabalin.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-Authorisation Safety Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX16) pregabalin

pregabalin

Population studied

Short description of the study population

The study population consists of all pregnancies identified in the respective administrative registries from 1 January 2005 to 31 December 2015 in Denmark, Finland, and Norway and all pregnancies identified from 1 July 2006 to 31 December 2013 in Sweden.

Patients meeting any of the following criteria will not be included in the study:

1. Pregnancies with exposure to known teratogenic medications during the first trimester;

2. Pregnancies carrying a foetus with a chromosomal abnormality diagnosis.

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)

Special population of interest

Pregnant women

Estimated number of subjects

900000

Study design details

Outcomes

major congenital abnormalities, Neurodevelopmental outcomes

Data analysis plan

Prevalence of each birth outcome will be computed as number of newborns with a given outcome divided by the total number of newborns at risk. For the outcomes of congenital malformations and stillbirth in the analysis not including pregnancies ending in 2nd trimester abortion the number of newborns at risk will be the total number of live or stillborn children. Incidence rate of each postnatal outcome will be computed as the number of first-recorded events during the follow-up divided by the total person-time at risk contributed by each liveborn infant. The follow-up for each newborn will begin on the date of birth and will end on the date of a given postnatal outcome, emigration, death, or the end of the observation period.Crude and adjusted prevalence ratios and 95% Wald confidence intervals (CIs) for each birth outcome and a given population/contrast will be estimated using log-binomial regression.Crude and adjusted incidence rate ratios and 95% Wald CIs will be estimated

Documents

Study results

A0081359 Pregabalin Final Study Report ABSTRACT VS1 01June2020.pdf (127.77 KB)

Study report

A0081359 Pregabalin Final Study Report VS1 01JUNE2020.pdf (633.6 KB)

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)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

NorPD, Drugs and Pregnancy Finland

Data sources (types)

Other

Data sources (types), other

This PASS is a population-based cohort study based on routinely collected data from administrative and medical registers in four Nordic countries: Denmark, Finland, Norway, and Sweden and will include all identifiable pregnancies between 2005 and up to 2015, followed up to 2016 (with actual period varying slightly by country)

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