

A Population-based Study of the Safety of Gabapentin Use During Pregnancy

First published: 11/12/2020

Last updated: 23/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS38620


Study ID

49994


DARWIN EU® study

No

Study countries

 Denmark

 Finland

 Norway

 Sweden

Study description

This non-interventional study is being conducted to characterize the use and safety of gabapentin during pregnancy

Study status

Finalised

Research institutions and networks

Institutions


Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

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

Multiple centres: 4 centres are involved in the study

Contact details

Study institution contact

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Study contact

kofi.asomaning@pfizer.com

Primary lead investigator

Asomaning Kofi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/12/2020

Actual: 21/12/2020

Study start date

Planned: 30/12/2020

Actual: 30/12/2020

Data analysis start date

Planned: 30/04/2021

Actual: 30/04/2021

Date of final study report

Planned: 31/03/2022

Actual: 08/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

[A9451182_Gabapentin_FINAL STUDY PROTOCOL_V1_02 October 2020 .pdf](#)

(414.03 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

A9451182

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This non-interventional study is being conducted to characterize the use and safety of gabapentin during pregnancy

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorisation safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX12) gabapentin

gabapentin

Population studied

Short description of the study population

The study population involved all births identified in the administrative registries from four Nordic countries including Denmark, Finland, Norway, and Sweden from 1 January 2005 to 31 December 2015.

Inclusion criteria:

1. All births from 1 January 2005 through 31 December 2015 (both dates inclusive) in Denmark, Finland, and Norway and all births identified from 1 July 2006 through 31 December 2016 (both dates inclusive) in Sweden.

Exclusion criteria:

1. Births with exposure to known teratogenic medications during the first trimester;
 2. Births with a chromosomal abnormality diagnosis.
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Age groups

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

Pregnant women

Estimated number of subjects

1700

Study design details

Outcomes

The primary study outcomes are: Major congenital malformations (overall and specific), Stillbirth, Low birth weight, Small for gestational age, Preterm birth, Low Apgar score at 5 minutes, Microcephaly, The secondary study outcomes are: Attention-deficit hyperactivity disorders, Pervasive developmental

disorders, Learning disorders and intellectual disabilities.

Data analysis plan

Descriptive statistics (ie, frequency, percent, mean, median, standard deviation as appropriate depending on data type) will be used to summarize demographic and baseline clinical characteristics of patients accrued in the study. Prevalence of each birth outcome will be computed as the number of newborns with a given outcome divided by the total number of newborns at risk.

Documents

Study report

[A9451182_GABAPENTIN NON-INTERVENTIONAL STUDY ABSTRACT_08 SEPT 2022.pdf](#) (1.9 MB)

[A9451182_GABAPENTIN NON-INTERVENTIONAL STUDY REPORT_08 SEPT 2022.pdf](#) (3.15 MB)

Study, other information

[A9451182_GABAPENTIN NON-INTERVENTIONAL STUDY ABSTRACT_08 SEPT 2022.pdf](#) (1.9 MB)

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret
Danish registries (access/analysis)

Data source(s), other

The Swedish prescribed drug register, Danish Registries (access/analysis),
NorPD

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Other](#)

Data sources (types), other

Prospective patient-based data collection

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