# 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

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**Study start date**
Planned: 30/12/2020

Actual: 30/12/2020

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**Data analysis start date**
Planned: 30/04/2021

Actual: 30/04/2021

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**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

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**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

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**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**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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**Special population of interest**

Pregnant women

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**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

## 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