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

PURI
https://redirect.ema.europa.eu/resource/49994

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 institution 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
Asomaning Kofi
Study contact
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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 data collection

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

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.

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
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)
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 data (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