Pregnancy, fetal and infant outcomes of pregnancies exposed to eptinezumab compared to two migraine control cohorts unexposed to eptinezumab: a claims database study in the United States

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000938

Study ID

1000000938

DARWIN EU® study

No

Study countries

United States

Study description

Retrospective cohort study of pregnant women with a diagnosis of migraine and treated with eptinezumab compared to two control cohorts: (1) Women with migraine who have been exposed to preventive migraine medications other than eptinezumab and other CGRP monoclonal antibodies before or during pregnancy (primary control cohort); (2) women with migraine who have not been exposed to eptinezumab or any preventive migraine medication (secondary control cohort)

Study status

Ongoing

Research institutions and networks

Institutions

H. Lundbeck

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Institution

Merative US L.P.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Non-interventional Research Manager H. Lundbeck A/S - Observational Research Committee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/03/2023

Actual: 03/03/2023

Study start date

Planned: 15/11/2023

Actual: 15/11/2023

Data analysis start date

Planned: 15/11/2023

Actual: 15/11/2023

Date of interim report, if expected

Planned: 31/12/2023

Actual: 05/12/2023

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Lundbeck A/S

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Pregnant women with migraine and their newborns are identified in healthcare databases. Study cohorts will be followed up throughout the pregnancy. Linked infants will be followed up for 12 months after birth.

Main study objective:

To assess pregnancy, fetal and infant outcomes of women with migraine exposed to eptinezumab during pregnancy compared to two unexposed control populations

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VYEPTI

Study drug International non-proprietary name (INN) or common name

EPTINEZUMAB

Anatomical Therapeutic Chemical (ATC) code

(N02CD05) eptinezumab

eptinezumab

Medical condition to be studied

Migraine

Pregnancy

Population studied

Short description of the study population

Pregnant patients with migraine, exposed to eptinezumab, other preventive migraine medications, or without exposure to preventive migraine medications

Age groups

- **In utero**
- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

4.004

Study design details

Setting

The study population will consist of pregnant women with migraine and their newborns in the US. The study will include women with pregnancy exposure to (1) eptinezumab; (2) other, non-CGRP-targeting, preventive migraine medications; or (3) without preventive migraine treatment.

Comparators

Non-CGRP targeting preventive migraine medications

Outcomes

Primary outcome: major congenital malformations. Secondary outcomes: pregnancy outcomes (spontaneous abortion; elective abortions; stillbirth; live birth); pre-eclampsia; eclampsia; infant outcomes (small-for-gestational-age, low birth weight, developmental delays during infancy, growth delays during

infancy)

Data analysis plan

Frequencies (prevalences) of outcomes will be presented as counts and percentages with 95% confidence intervals. When feasible, comparative analyses will be conducted based on the ratios of prevalences. Potential confounding will be controlled for by using propensity score based methods.

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)

Other data source

Data source(s), other

Merative Marketscan Commercial Database

Merative MarketScan Multi-state Medicaid Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No