Vyepti Pregnancy Registry: A prospective, comparative cohort study of maternal, fetal and infant safety in pregnant women exposed to eptinezumab in the United States

First published: 18/02/2026

Last updated: 19/02/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000936

Study ID

1000000936

DARWIN EU® study

No

Study countries

United States

Study description

National, prospective cohort study in pregnant women with migraine exposed to eptinezumab or non-CGRP targeting preventive migraine medications, during pregnancy or up to 5 drug half-lives prior to the estimated conception date. Patients will be included in an US national pregnancy registry and followed-up until end of pregnancy. In case of a live birth, additional follow-up for 12 months will be conducted to collect information on infant health and development.

Study status

Ongoing

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

H. Lundbeck

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

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Study contact

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Primary lead investigator

Amy Miller

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2022

Actual: 03/08/2022

Study start date

Planned: 30/05/2024

Actual: 30/09/2024

Date of interim report, if expected

Planned: 31/12/2023

Actual: 05/12/2023

Date of final study report

Planned: 31/12/2036

Sources of funding

- Pharmaceutical company and other private sector

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:

Primary data collection

Study design:

National, prospective cohort study in pregnant women with migraine exposed to eptinezumab or non-CGRP targeting preventive migraine medications, during pregnancy or up to 5 drug half-lives prior to the estimated conception date.

Main study objective:

To estimate and compare the frequency (prevalence) of major congenital malformations (MCM) in women with migraine exposed to eptinezumab during pregnancy; and women with migraine exposed to non-CGRP targeting preventive migraine medications during pregnancy

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 or other preventive migraine medications

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Age groups

- **In utero**
- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adolescents (12 to < 18 years)
- **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

844

Study design details

Setting

The study will include migraine patients exposed to eptinezumab or non-CGRP targeting preventive migraine medications during pregnancy. The study will include prospectively and retrospectively reported pregnancies. The main analysis will be conducted based on prospectively reported pregnancies.

Comparators

Non-CGRP targeting preventive migraine medications

Outcomes

Primary outcome: major congenital malformations (MCM)

Secondary outcomes: adverse pregnancy outcomes (e.g., spontaneous abortions, stillbirths); pregnancy complications; adverse fetal/neonatal/infant outcomes (e.g., during postnatal growth and development)

Data analysis plan

The ratio of the MCM prevalences will be used to estimate the relative risk of MCM. In addition to the estimation of unadjusted relative risks with corresponding 95% CIs, propensity score based methods are planned to conduct adjusted analyses.

Documents

https://Vyeptipregnancyregistry.lundbeck

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

Vyepti Pregnancy Registry

Data sources (types)

Pregnancy registry

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