

# Observational Study to Assess Maternal, Fetal, and Infant Outcomes Following Exposure to Erenumab-aooe During Pregnancy (20180172)

**First published:** 14/10/2020

**Last updated:** 22/11/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS37499

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### Study ID

39424

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

This study is being conducted to understand the safety of administering erenumab-aooe during pregnancy. Data will be collected from two large US administrative claims databases to allow for longitudinal follow-up of patient outcomes. Data from pregnant women with migraines aged 16 to 44 and their infants will be included in this study. The planned study period is approximately 9.5 years, from May 2018 to November 2027. This study will provide an assessment of erenumab-aooe utilization patterns versus other preventive and acute medications being used by pregnant women suffering from migraines. This study aims to assess the safety of erenumab-aooe on maternal, fetal, and infant outcomes resulting from the use of erenumab-aooe during pregnancy.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

Amgen

United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

**Primary lead investigator**

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 05/11/2019

Actual: 05/11/2019

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**Study start date**

Planned: 01/02/2021

Actual: 04/02/2021

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**Data analysis start date**

Planned: 01/11/2027

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**Date of interim report, if expected**

Planned: 30/11/2021

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**Date of final study report**

Planned: 30/11/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

## Study protocol

[Protocol-Published Original erenumab 20180172 .pdf](#) (5.92 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Other study registration identification numbers and links

Protocol number - 20180172

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To estimate and compare the proportion of live-born infants with major congenital malformations among women with migraine directly exposed to erenumab-aooe prior to and during pregnancy, women with migraine exposed to other preventive migraine medications prior to or during pregnancy, and women with migraine not exposed to any preventive migraine medications prior to or during pregnancy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

AIMOVIG

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

ERENUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(N02CD01) erenumab

erenumab

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## **Medical condition to be studied**

Migraine

## Population studied

### **Age groups**

- Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

1500

## Study design details

### **Outcomes**

To estimate and compare the proportion of live-born infants with major congenital malformations. To estimate and compare the proportion of pregnancies ending in spontaneous abortions, and, separately, stillbirths. To

estimate and compare the proportion of live-born infants who are small-for gestational age. To describe baseline characteristics and medication treatment patterns during pregnancy.

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### **Data analysis plan**

Discrete variables will be summarized using frequencies and proportions, and continuous variables will be summarized using means and standard deviation or medians and interquartile range, as appropriate. Demographic and other baseline characteristics will be summarized by cohort of exposure. Each of the primary and secondary outcomes will be described using frequencies, proportions and corresponding 95% confidence intervals (CI). If there is sufficient sample size, formal comparisons to estimate risk (odds ratios and corresponding 95% CIs) will be undertaken, using standardized mortality ratio weights to account for confounding.

## 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**

MarketScan CCE database

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## **Data sources (types)**

Administrative healthcare records (e.g., claims)

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No