# 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





# Administrative details

**Study description** 

| EU PAS number    |  |
|------------------|--|
| EUPAS37499       |  |
|                  |  |
| Study ID         |  |
| 39424            |  |
| DARWIN EU® study |  |
| _                |  |
| No               |  |
| Study countries  |  |
| United States    |  |
|                  |  |
|                  |  |

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.

#### **Study status**

Ongoing

### Research institutions and networks

#### **Institutions**

# Amgen United States First published: 01/02/2024 Last updated: 21/02/2024 Institution

### Contact details

**Study institution contact** 

# Global Development Leader Amgen Inc. medinfo@amgen.com

Study contact

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

#### Study start date

Planned: 01/02/2021 Actual: 04/02/2021

#### Data analysis start date

Planned: 01/11/2027

#### Date of interim report, if expected

Planned: 30/11/2021

#### 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

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

#### 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** 

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

**ERENUMAB** 

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

(N02CD01) erenumab erenumab

#### 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)</li>
- Adults (18 to < 46 years)</li>

#### Special population of interest

Pregnant women

#### **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.

#### 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

#### 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

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

#### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No