# GENESIS: AIMOVIG® Pregnancy Exposure Registry (20180125)

**First published:** 06/11/2020

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## Administrative details

EU PAS number	
EUPAS37799	
Church ID	
Study ID	
39266	
DARWIN EU® study	
No	
Study countries	
Study countries	
United States	

#### **Study description**

This study will address a requirement by the Food and Drug Administration (FDA) to conduct a prospective observational study of pregnant women exposed to erenumab-aooe (Aimovig ®) to evaluate maternal, fetal, and infant

outcomes. This study is being conducted to understand the safety of administering erenumab-aooe during pregnancy in women. Data from pregnant women who are eighteen years or older, experience migraines, and were exposed to erenumab-aooe, and their infants will be included in this study. The erenumab-aooe exposed cohort will be compared with two unexposed comparator cohorts: 1) women with migraine who have not been exposed to erenumab-aooe before or during pregnancy (internal comparator), and 2) pregnant women without migraine (external comparator). The planned study period is approximately 7 years. The total duration per patient will be up to 21 months. The registry will identify and record pregnancy complications, major and minor congenital malformations, spontaneous abortions, still births, elective terminations, preterm births, small-for-gestational age births, postnatal growth and development deficiency, and any other adverse outcomes.

#### **Study status**

Ongoing

#### Research institutions and networks

## Institutions

Amgen
United States
First published: 01/02/2024
<b>Last updated:</b> 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: 20/08/2018 Actual: 20/08/2018

Study start date

Planned: 25/01/2021

Actual: 27/01/2021

#### **Data analysis start date**

Planned: 30/11/2027

#### Date of interim report, if expected

Planned: 30/11/2024

#### **Date of final study report**

Planned: 30/11/2028

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

Protocol-Published Original erenumab 20180125 .pdf (2.16 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 20180125

## 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:

This study will address a requirement by the Food and Drug Administration (FDA) to conduct a prospective observational study of pregnant women exposed to erenumab-aooe to evaluate maternal, fetal, and infant outcomes.

## Study Design

#### Non-interventional study design

Cohort

## Study drug and medical condition

#### Name of medicine

**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)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

1421

## Study design details

#### **Outcomes**

The primary objective is to estimate the proportion of major congenital malformations in infants of women with migraine exposed to erenumab-aooe during pregnancy compared to infants of women with migraine unexposed to erenumab-aooe (internal comparator). In women exposed to erenumab-aooe during pregnancy, estimate and compare the proportion of pregnancy complications, spontaneous abortions, stillbirths, elective terminations, and preterm birth. In infants, estimate and compare the proportion of small-forgestational age, minor congenital malformations, and postnatal growth and development deficiency through the first year of life.

#### Data analysis plan

To describe baseline patient characteristics, continuous variables will be reported as mean (standard deviation), median, minimum, maximum and range, and categorical variables will be summarized as number and proportion of the total study population. The overall frequency (proportion, 95% confidence interval CI) of select maternal, fetal, and infant outcomes will be calculated. Primary and secondary outcome frequencies in the erenumab-aooe exposed cohort will be compared with the internal comparator cohort using the risk ratio (95% CIs).

## 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 sources (types)**

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