GENESIS: AIMOVIG® Pregnancy Exposure Registry (20180125)

First published: 06/11/2020

Last updated: 22/05/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39266

EU PAS number

EUPAS37799

Study ID

39266

DARWIN EU® study

No

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

Last updated: 21/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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-for-gestational 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

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