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

PURI

https://redirect.ema.europa.eu/resource/39424

EU PAS number

EUPAS37499

Study ID

39424

DARWIN EU® study

No

Study countries

United States

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.

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.

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

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)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

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

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