Evolocumab Pregnancy Exposure Registry: An OTIS Pregnancy Surveillance Study (20150338)

First published: 01/12/2016

Last updated: 30/10/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS16049

Study ID

38953

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

This study was terminated prematurely and there were 0 exposed subjects and therefore no results to report.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Networks

Organization of Teratology Information Specialists (OTIS) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

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: 01/10/2016

Actual: 20/10/2016

Study start date

Planned: 22/12/2016

Actual: 22/12/2016

Data analysis start date

Planned: 08/06/2032

Actual: 22/07/2020

Date of final study report

Planned: 14/02/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

Protocol-Published Original evolocumab 20150338 .pdf(1.55 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

Primary scope is to evaluate the safety of Repatha in pregnant women and their pregnancy outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

REPATHA

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

EVOLOCUMAB

Anatomical Therapeutic Chemical (ATC) code

(C10AX13) evolocumab

evolocumab

Medical condition to be studied

Hypercholesterolaemia

Pregnancy

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

375

Study design details

Setting

A prospective observational study of pregnant women exposed to evolocumab to evaluate fetal, infant & childhood outcomes of these women & their live born offspring through the first 5 years of life to estimate incidence rates for potential safety signals of adverse pregnancy outcomes, embryo-fetal growth and development, & adverse infant and childhood outcomes related to humoral immune suppression.

Outcomes

To estimate the overall combined rate of major structural defects in infants of women with ASCVD and/or familial hypercholesterolemia (FH) exposed to evolocumab during pregnancy. Any major structural defects will be classified by a study investigator according to the Centers for Disease Control (CDC) Coding Manual: Abortion (spontaneous and elective), stillbirth, premature delivery, minor structural defects, size at gestational age, postnatal growth deficiency, postnatal serious infections, infant vaccination reactions, IgG-tetanus antibody response, adverse neurodevelopmental outcomes, breastfeeding outcomes

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Data analysis plan

All statistical analyses will be performed at the 0.05 significance level using 2-sided tests or 2-sided 95%confidence intervals (CIs) unless otherwise specified. Demographics and baseline characteristics will be summarized.All continuous variables will be summarized using the following statistics: Number of non-missing data, Mean, Standard Deviation, Median, Minimum, Maximum, 1st quartile, 3rd quartile. All categorical variables will be summarized using counts and percentages. Missing data or unknown responses will not be counted in the percentages. e.g. risk estimation, measures of risk, internal/external validity.

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