Characterizing Repatha use among adult pregnant women, adult women of childbearing age and within the adult general population (NA)

First published: 27/06/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS30072

Study ID

40717

DARWIN EU® study

No

Study countries

Denmark

Germany

Norway

Sweden

United Kingdom

United States

Study description

To describe the use of Repatha among adult (≥16 years of age) pregnant women, adult women of childbearing age (16-54 years) and within the adult general population.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

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: 01/01/2019

Actual: 01/01/2019

Study start date

Planned: 15/07/2019

Actual: 15/07/2019

Data analysis start date

Planned: 01/05/2020

Actual: 01/05/2020

Date of final study report

Planned: 30/03/2021

Actual: 08/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20190050_01.02.06 Public Redacted Protocol Ver 1.0 2019-05-09 English.pdf (3.6 MB)

20190050-protocol_public-redacted-approved-version_August 2019.pdf (459.85 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Characterizing Repatha use among adult pregnant women, adult women of childbearing age and within the adult general population

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

REPATHA

Anatomical Therapeutic Chemical (ATC) code

(C10AX13) evolocumab

evolocumab

Population studied

Short description of the study population

We will identify three cohorts of patients. The first is a cohort of adult (>16 years of age) pregnant women. The second is a cohort of adult women of childbearing age (ages 16-54 years). The third is a cohort of adults in the general population.

Inclusion Criteria:

Pregnant Women Cohort

1. Female
2. 16 years of age or older (as of August 27, 2015 or July 17, 2015)
3. Have at least one birth (live or non-live) claim during the study period (August 27, 2015 or July 17, 2015 until the end of available data)
4. Have continuous medical and pharmacy health insurance coverage during the 480 days (includes up to 300 pregnancy days + 180 days prior to the estimated date of conception) prior to the birth claim, with an allowable 45-day gap in coverage.

Women of Childbearing Age Cohort

1. Female
2. 16 to 54 years of age (as of August 27, 2015 or July 17, 2015)

General Population Cohort

1. 16 years of age or older (as of August 27, 2015 or July 17, 2015)

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Pregnant women

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

0

Study design details

Data analysis plan

To estimate the number of exposures, duration of each exposure(s) and frequency of dosing of Repatha among pregnant women, women of childbearing age and in the general population. Among those exposed to Repatha, we will further characterize these patients by age, calendar year of exposure(s), history of ASCVD (yes/no), gender (for the general population only) and by trimester of exposure(s) (for the pregnant women cohort only).

Documents

Study results

20190050 ORSR Abstract_FINAL_2.pdf (139.07 KB)

Data management

Data sources

Data source(s), other

Clinical Practice Research Datalink (CPRD), IQVIA Disease Analyzer Germany

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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