A Multinational Observational Study to Evaluate the Safety of Repatha® in Pregnancy (20150162)

First published: 17/09/2016

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40671

EU PAS number

EUPAS15153

Study ID

40671

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Slovakia
- [ ] South Africa
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

To evaluate outcomes of pregnancy in females diagnosed with familial hypercholesterolaemia (FH), exposed to Repatha® during pregnancy. This includes follow-up of their infants to the age of 12 months.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 70 centres are involved in the study

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: 05/09/2016

Actual: 05/09/2016

Study start date
Planned: 30/09/2016

Actual: 12/01/2017

Data analysis start date
Planned: 21/12/2020

Actual: 21/12/2020

Date of interim report, if expected
Planned: 30/09/2019

Date of final study report
Planned: 06/05/2021

Actual: 02/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc

Study protocol

20150162_PASS Protocol_17May2016_Final_Redacted.pdf(1.02 MB)

01.02.06 Public Redacted Protocol Ver 1.0 English_18Dec2018_20150162.pdf
(1.74 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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Scope is to evaluate the safety of Repatha in pregnancy, primary scope is to describe outcomes of pregnancy in FH women exposed to Repatha

Data collection methods:

Primary data collection

Main study objective:

To evaluate outcomes of pregnancy in females diagnosed with familial hypercholesterolaemia (FH), exposed to Repatha® during pregnancy. This includes follow-up of their infants to the age of 12 months

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

Population studied

Short description of the study population

Sunjects were females diagnosed with Familial hypercholesterolaemia with a confirmed pregnancy during the study observation period and who provided informed consent to follow-up in this study, for themselves and their infants born during the study observation period.

Inclusion Criteria

1. Females diagnosed with FH
2. Confirmed pregnancy during the study observation period
3. Pregnancies identified retrospectively but within the study period will be included
4. Multiple pregnancies, occurring in the same woman within the study period, will all be included (as separate pregnancies)
5. Provided informed consent to follow-up in this study, for subject and their infant(s) born during the study observation period

Exclusion Criteria

There are no exclusion criteria

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

300

Study design details

Outcomes

The primary outcome measure is congenital anomaly. Any incidence of congenital anomaly will be diagnosed and classified by the study site investigator, or by the subject’s treating physician (eg. An obstetrician, paediatrician, neonatologist) if this is not the investigator, and reported on the study specific eCRF. • Pregnancy outcomes (live birth(s),stillbirth,spontaneous loss,elective termination,ectopic pregnancy,complications of pregnancy• Delivery outcomes (mode of delivery, complications including requirement for blood transfusion, thromboembolism, fetal distress, amniotic fluid abnormality)• Infant status at delivery• Infant outcomes at 6 and 12 months post-delivery

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Data analysis plan

Statistical analyses will be descriptive only. No statistical inference or imputations of missing data are planned.Subject demographics and baseline characteristics will be summarised. Summary statistics for continuous variables will include the number of subjects, mean, median, standard deviation or standard error, minimum, and maximum. For categorical variables, the frequency and percentage will be reported.Collection of study data may be both retrospective and/or prospective, depending on the time of enrolment of each study subject during the study observation period. Data obtained from retrospective and prospective subject identification will be reported separately.

Documents

Study results

20150162_Abstract Observational Research Study Report Published Report.pdf
(544.52 KB)

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