Observational Serial Chart Review of Repatha® Use in European Subjects with Hyperlipidaemia (20130296)

First published: 28/04/2016

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47822

EU PAS number

EUPAS13328

Study ID

47822

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Belgium
- [ ] Bulgaria
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Portugal
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland

Study description

Review of clinical characteristics of patients who are prescribed Repatha and how their treatment is managed.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 250 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: 18/12/2015

Actual: 18/12/2015

Study start date

Planned: 29/04/2016

Actual: 04/05/2016

Data analysis start date
Planned: 26/07/2021

Actual: 13/09/2021

Date of final study report
Planned: 30/05/2022

Actual: 24/05/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc

Study protocol

01.20.01 Protocol Ver 1.0 2015-11-19 English.pdf(1.11 MB)

20130296_01.02.06 Public Redacted Protocol Ver 1.0 2018-12-20 English.pdf
(1.4 MB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

To describe clinical characteristics of subjects using Repatha

Data collection methods:

Primary data collection

Main study objective:

To ascertain the clinical characteristics of patients who are prescribed Repatha® in the post-launch period, and how their treatment is managed

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multicountry, observational, serial chart review

Study drug and medical condition

Medical condition to be studied

Hyperlipidaemia

Population studied

Short description of the study population

Patients receiving Repatha® as part of routine clinical management of their hyperlipidaemia.

All inclusion criteria need to be met, as follows:

• Adults (≥ 18 years)

• Provided informed consent if applicable according to local requirements

• Initiated on Repatha® at physician’s discretion, after 1st August 2015

• Received at least one dose of Repatha®

Exclusion Criteria

If at least one exclusion criterion is met, subject is not eligible for participation in the study, as follows:

• Enrolled in an interventional study of PCSK9 inhibitor within 12 weeks prior to initiation of Repatha®

• Received commercially available PCSK9 inhibitor within 12 weeks prior to initiation of Repatha®

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)

Estimated number of subjects

2000

Study design details

Outcomes

To describe the clinical characteristic of subjects at initiation of Repatha®, To describe LDL-C and other cholesterol concentrations over time To described treatment patterns of use of Repatha® over time To describe treatment patterns of use of other lipid modifying therapies over time To describe Health Resource Utilisation components, including hospitalisations and physician visits

Data analysis plan

All summaries of the data will be descriptive in nature. For categorical variables the frequency and percentage, with 95% confidence interval, will be given. Summary statistics for continuous variables will include the number of subjects, mean, median, standard deviation or standard error, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum. Regarding the primary endpoints, summaries displaying frequency and percentage, with 95% confidence intervals will be presented for FH status, CV history and diabetic status at the time of initiation of Repatha®, while summary statistics displaying the number of subjects, mean, median, standard deviation, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum will be presented for LDL-C at the time of initiation of Repatha®. The primary intention is to analyse data for each country separately, but the final analysis will also be conducted for all countries pooled.

Documents

Study results

Observational Research Study Report 20130296_Redacted.pdf(147.65 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