A post-marketing surveillance study for Repatha Inj. (evolocumab) in Korea text (20160156)

First published: 25/07/2017

Last updated: 05/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/29447

EU PAS number

EUPAS19680

Study ID

29447

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

To assess the safety and efficacy of Repatha in post-marketing routine clinical settings as required by the Ministry of Food and Drug Safety.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Multiple centres: 30 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: 01/11/2017

Actual: 01/11/2017

Study start date

Planned: 29/03/2019

Actual: 09/04/2019

Data analysis start date

Planned: 20/02/2023

Actual: 27/01/2023

Date of final study report

Planned: 12/07/2023

Actual: 07/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Repatha PMS_20160156_ver 1 redacted.pdf(670.63 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to assess the incidence rate of adverse events (AEs) (including device related AEs) and adverse drug reactions (ADRs) for up to 12 weeks in patients who are prescribed Repatha according to the approved therapeutic indications, dosage, and administration in post-marketing settings

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single arm, prospective, observational study

Study drug and medical condition

Name of medicine

REPATHA

Medical condition to be studied

Hyperchloraemia

Population studied

Short description of the study population

Adults and adolescents aged 12 years or older with homozygous familial hypercholesterolemia (HoFH) received treatment with Repatha under routine clinical settings in Korea.

Inclusion criteria:

 HoFH patient treated with Repatha Inj. according to the approved therapeutic indications, dosage, and administration in post-marketing settings

 Patient who voluntarily provided written informed consent

Exclusion criteria:

 Patient who did not provide written informed consent

 There are no other exclusion criteria.

Age groups

Adolescents (12 to < 18 years)

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

Other

Special population of interest, other

Patients with homozygous familial hypercholesterolemia

Estimated number of subjects

10

Study design details

Outcomes

incidence rate of AEs/ADRs observed or reported to the investigator during the follow-up period, Efficacy measurement, change in low-density lipoprotein (LDL)-cholesterol (LDL-C) measured as part of routine clinical practice from baseline to the end of follow-up, patient demographic information and medical history, diagnosis of hypercholesterolemia, concomitant medication prior to study participation, other concomitant medication

Data analysis plan

Categorical variables will be summarized with frequency and percentage, and continuous variables will be summarized with mean, standard deviation (SD), standard error (SE), median, Q1, Q3, minimum, and maximum. Subject disposition, demographic information, and baseline characteristics will be summarized in the safety set. For safety analysis, number of subjects, number of events, and incidence rate will be presented in the safety set for AEs (including device related AEs), ADRs, and serious AEs (SAEs). 95% confidence interval will not be calculated because it is not meaningful for the planned sample size of 10 subjects. For efficacy analysis, change (%) in LDL-C at Week 12 from baseline will be analysed in the efficacy set.

Documents

Study results

20160156 ORSR_Redacted.pdf(171.48 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