Long Term Post Marketing Specified Drug Use Result Survey for Evolocumab in Japan (20140409) (Evolocumab Long term PMS Japan)

First published: 03/06/2016

Last updated: 22/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13676

Study ID

17126

DARWIN EU® study

No

Study countries

☐ Japan

Study description

To assess the safety and effectiveness in the patients with familial hypercholesterolemia (heterozygous or homozygous) and hypercholesterolemia for long term (2years) treatment of evolocumab injection in a real world medical practice in Japan, with particular focus on the safety specifications as described in Japanese Risk Management Plan, hypersensitivity and immunogenicity as important potential risks, and use in the following patient sub-populations as important missing information: patients with homozygous familial hypercholesterolemia including pediatric, elderly patients ≥ 75 years old, patients with hepatic impairment, patients with hepatitis C, and long-term use including effects of persistent LDL-C level < 40 mg/dL (< 1.0 mmol/L).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

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: 21/04/2016

Actual: 17/07/2015

Study start date

Planned: 06/06/2016

Actual: 24/06/2016

Data analysis start date

Planned: 23/01/2023

Actual: 04/08/2023

Date of final study report

Planned: 30/06/2023

Actual: 11/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

Study_20140409_Evolocumab_Japan_PMS_Protocol_Amgen Format_ver2_20160513 - Clean.pdf(1.59 MB)

Study_20140409_Evolocumab_Japan_PMS_Protocol_Amgen Format_ver2_20160525.pdf(1.66 MB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To determine the incidence of adverse events and adverse drug reactions (adverse events for which causal relation to evolocumab cannot be ruled out) among patients receiving evolocumab for up to 2 years, and to identify and describe patient characteristics associated with the safety and effectiveness of evolocumab therapy.

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

Additional medical condition(s)

Familial hypercholesterolemia (heterozygous or homozygous)

Population studied

Short description of the study population

Patients for whom evolocumab is prescribed at participating medical institutions in accordance with the approved Japan prescribing information.

Age groups

Children (2 to < 12 years)

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

Hepatic impaired

Renal impaired

Estimated number of subjects

6000

Study design details

Outcomes

Incidence (%), number of patients and number of events per 1,000 person-years with adverse drug reactions and serious adverse events during the observational period (up to 2 years), and Percent change in LDL-C from baseline to Week 12,
Incidence (%), number of patients and number of events per 1,000 person-years with adverse drug reactions and serious adverse events in sub-population of patient characteristics, including the patient sub-populations specified as important missing information

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Data analysis plan

A descriptive analysis is conducted. Categorical variables are summarized with frequencies and percentage. Continuous variables are summarized with mean, standard deviation (SD), median, 1st Quartile (Q), and 3rd Q.When statistical testing and inference are applied, two-sided p-value of <0.05 is considered significant and the 95% confidence interval (CI) is estimated. Adjustment for multiple comparisons is not considered.

Documents

Study report

20140409 ORSR abstract.pdf(270.83 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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