Specific Drug Use-results Surveillance (Long-term) for Erenumab in Migraine Patients in Japan (20210048)

First published: 26/01/2022

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Study Planned

Administrative details

EU PAS number

EUPAS45236

Study ID

45964

DARWIN EU® study

No

Study countries

Japan

Study description

To describe the occurrence of hypertension and cardiovascular events in patients treated with erenumab and to describe the safety and efficacy of long-term treatment with erenumab under real-world conditions.

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Chiba University Hospital Chiba, Japan

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: 12/02/2022

Study start date
Planned: 20/02/2022

Data analysis start date
Planned: 30/08/2028

Date of final study report
Planned: 30/08/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original erenumab 20210048 .pdf (1.98 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)

Study design:

This is an observational prospective cohort study of patients with migraine treated with erenumab in a real-world setting.

Main study objective:
To describe the occurrence of hypertension and cardiovascular events in patients treated with erenumab and to describe the safety and efficacy of long-term treatment with erenumab under real-world conditions.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
AIMOVIG

Study drug International non-proprietary name (INN) or common name
ERENUMAB

Anatomical Therapeutic Chemical (ATC) code
(N02CD01) erenumab
erenumab

Medical condition to be studied
Migraine

Population studied

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)

Estimated number of subjects

1300

Study design details

Outcomes

• Patient incidence of adverse drug reaction

• Patient incidence of adverse event

• Patient incidence of adverse drug reaction regarding safety specifications

• Patient incidence of adverse drug by patient background and characteristics (such as sex, age, disease duration, medical history)

• Patient incidence of adverse drug by time of onset

Data analysis plan

For safety analysis, the number of patients with adverse drug reactions and serious adverse drug reactions during the observation period and the incidence in all patients will be tabulated. The same analyses will be performed for adverse events, serious adverse events, etc.

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