

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

**First published:** 26/01/2022

**Last updated:** 22/05/2024

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.

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## Study status

Planned

## Research institutions and networks

### Institutions

[Amgen](#)

☐ United States

**First published:** 01/02/2024

**Last updated:** 21/02/2024

**Institution**

[Chiba University Hospital Chiba, Japan](#)

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
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#### Study contact

[medinfo@amgen.com](mailto: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

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#### Study start date

Planned: 20/02/2022

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#### Data analysis start date

Planned: 30/08/2028

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#### 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

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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##### **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

### **Name of medicine**

AIMOVIG

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

ERENUMAB

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### **Anatomical Therapeutic Chemical (ATC) code**

(N02CD01) erenumab

erenumab

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### **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)

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## **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
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## **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

## Data sources

## **Data sources (types)**

Other

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No