

# Risk of Hypertension, Acute Myocardial Infarction, and Stroke in Migraine Patients Treated With Migraine Preventive Medications (20200403)

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS45799

### Study ID

47658

### DARWIN EU® study

No

### Study countries

☐ United States

### Study status

Finalised

## Research institutions and networks

## Institutions

Amgen

☐ United States

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

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Institution

NoviSci Durham, NC, USA

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
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Study contact

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### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 15/02/2022

Actual: 15/02/2022

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**Study start date**

Planned: 31/03/2022

Actual: 31/03/2022

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**Data analysis start date**

Planned: 01/06/2022

Actual: 09/06/2022

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**Date of final study report**

Planned: 01/06/2023

Actual: 01/06/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen, Novartis

## Study protocol

[EUPAS45799-46045.pdf](#)(2.11 MB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe baseline characteristics of four cohorts of migraine patients initiating a migraine preventive treatment: erenumab-aooe, other mAbs

targeting the CGRP pathway, selected SOC migraine preventive medications (anti-epileptics), and onabotulinumtoxinA.

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Observational retrospective study

## Study drug and medical condition

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

ERENUMAB

FREMANEZUMAB

GALCANEZUMAB

EPTINEZUMAB

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### **Medical condition to be studied**

Migraine

Hypertension

Acute myocardial infarction

Cerebrovascular accident

## Population studied

## **Short description of the study population**

The study included four migraine-related cohorts using data from the MarketScan Commercial and Medicare Supplemental medical claims database. The cohorts included patients aged 18-64 with migraines, using erenumab-aooe, other mAbs targeting the CGRP pathway, standard of care migraine preventive medications, and onabotulinumtoxinA from 17 May 2018 to 31 May 2020.

### **Inclusion Criteria:**

1. 18-64 years of age on the index date.
2. One year of continuous enrollment (ie, complete medical and pharmacy coverage) prior to and including the index date, which defines the baseline period.
3. A diagnosis of migraine during the baseline period, based on one of the following criteria:
  - a)  $\geq 1$  inpatient claim with a diagnosis of migraine (ICD-10-CM) diagnosis code of G43.xxx).
  - b)  $\geq 1$  outpatient evaluation and management claim with a diagnosis of migraine and a specialty code of 260 (neurologist).
  - c)  $\geq 1$  claim for emergency room visit with a diagnosis of migraine.
  - d)  $\geq 1$  outpatient evaluation and management claim with a diagnosis of migraine PLUS <sup>3</sup>1 pharmacy fill for a migraine-specific triptan or an ergotamine class medication within 365 days of each other
  - e)  $\geq 2$  outpatient evaluation and management claims with a diagnosis of migraine between 7 and 365 days apart.
  - f)  $\geq 2$  pharmacy fills for migraine-specific triptans or ergotamine class medications between 7 and 365 days apart.

### **Exclusion Criteria:**

- (1) For the new user cohorts of mAbs targeting the CGRP pathway, no use of

any medication targeting the CGRP pathway (erenumab-aooe, galcanezumab-gnlm, fremanezumab-vfrm, eptinezumab-jjmr, ubrogepant, rimegepant) in the year prior to the index date.

(2) For the SOC migraine preventive medications (anti-epileptics) new user cohort, no use of any of the migraine preventive anti-epileptics: (topiramate, valproic acid, divalproex sodium), or any medication targeting the CGRP pathway in the year prior to the index date.

(3) For the onabotulinumtoxinA new user cohort, no use of any onabotulinumtoxinA or any medication targeting the CGRP pathway in the year prior to the index date.

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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with hypertension, myocardial infarction and stroke

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### **Estimated number of subjects**

56000

## **Study design details**

### **Outcomes**

Incidence of Hypertension, Acute MI, and Stroke in migraine patients treated with erenumab-aooe, other mAbs targeting the CGRP pathway, selected SOC

migraine preventive medications (anti-epileptics), and onabotulinumtoxinA. Also to separately compare the cumulative incidence of select negative control outcomes in those patient groups.

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### **Data analysis plan**

For the primary analysis, we will describe baseline patient characteristics, and estimate the risk of three CV outcomes (hypertension, stroke, acute MI) in the following four new user cohorts: (1) erenumab-aooe, (2) other mAbs targeting the CGRP pathway, (3) select anti-epileptic medications, and (4) onabotulinumtoxinA. If appropriate based on comparability analyses, we will also separately compare the risk of acute MI and stroke in patients treated with erenumab-aooe to the risk in each of the other three medication cohorts.

## Documents

### **Study results**

[20200403 ORSR\\_Redacted.pdf](#)(293.17 KB)

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## 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 source(s), other**

The MarketScan Commercial and Medicare Supplemental medical claims database United States

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## 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