Risk factors and incidence of inpatient constipation and inpatient constipation with serious complications among migraine patients treated with erenumab: A retrospective cohort study in a US Electronic Health Record Database (20200087)

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# Administrative details

**EU PAS number** 

**EUPAS34220** 

**Study ID** 

40638

**DARWIN EU® study** 

No

# Study countries United States

### **Study description**

This retrospective observational study will describe the incidence and risk factors for inpatient constipation and inpatient constipation with serious complications among migraine patients treated with erenumab to give context to events observed in the clinical trials as well as real-world observations from post-marketing surveillance data.

### **Study status**

**Finalised** 

### Research institutions and networks

### **Institutions**

Amgen
United States
First published: 01/02/2024
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Institution

Opum, Inc Eden Praire, Minnesota

### Contact details

### **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

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: 06/12/2019

Actual: 06/12/2019

### Study start date

Planned: 01/04/2020

Actual: 01/04/2020

### Data analysis start date

Planned: 02/04/2020

Actual: 01/05/2020

### **Date of final study report**

Planned: 01/05/2021

Actual: 20/04/2021

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Amgen

# Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 2020-03-15 English.pdf (204.71 KB)

# Regulatory

Was the study required by a regulatory body?

No

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

### Study type:

Non-interventional study

### Scope of the study:

Disease epidemiology

### **Data collection methods:**

Secondary use of data

### Main study objective:

1. To describe risk factors of inpatient constipation and inpatient constipation with serious complications among migraine patients treated with erenumab. 2. To estimate the cumulative incidence proportion of inpatient constipation and inpatient constipation with serious complications among migraine patients treated with erenumab.

# Study Design

### Non-interventional study design

Cohort

Other

### Non-interventional study design, other

Retrospective, Electronic Health Record database

# Study drug and medical condition

### Medicinal product name

### Medical condition to be studied

Migraine

# Population studied

### Short description of the study population

The study population will include patients with a migraine diagnosis on or prior to receiving a prescription order for erenumab identified from 17 May 2018 through 30 June 2019 (or latest available data). Patients receiving erenumab will be identified using National Drug Codes (NDC) as recorded in the prescription order table within the EHR database. Migraine patients will be identified using a combination of ICD-10-CM migraine diagnosis codes (G43.-) and acute migraine-specific medication (triptans or ergots). To be included, patients must be at least 18 years or older at the time of the erenumab prescription order and have at least one outpatient clinical visit at least one year prior to the index date to establish baseline medications, risk factors, and patient characteristics. The minimum time requirement for establishing baseline factors may change due to sample size considerations. We will examine the number of patients who have a visit at least 6, 9, and 12 months prior to their index date. The index date will be defined as the date of the earliest prescription order for erenumab that meets all these criteria.

### Age groups

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)</li>

• Adults (85 years and over)

### **Special population of interest**

Other

### Special population of interest, other

Migrane patients

### **Estimated number of subjects**

18941

# Study design details

### **Outcomes**

The cumulative incidence proportion of inpatient constipation and inpatient constipation with serious complications

### Data analysis plan

Risk of inpatient constipation (IC) (and the subset with serious complications) among the erenumab cohort will be described overall and stratified by the presence/absence of gastrointestinal conditions or other comorbidities in the baseline period. The erenumab cohort will be described by frequencies and percentages according to demographics and other baseline risk factors. Counts of IC events (and the subset with serious complications) observed starting from the day after index date through the end of study period (or switching to another anti-CGRP) will be tabulated. Only the first observed IC event will be counted. The cumulative incidence proportion of IC (and the subset with serious complications) will be calculated as the number of events identified during follow-up divided by the number of patients at risk for the event (along with 95% confidence intervals). Study results will be applicable to migraine patients

initiating erenumab in the United States.

### **Documents**

### **Study results**

01.47.01.01 Observational Research Study Report Published Report\_Abstract (2020087)\_Redacted.pdf (154.25 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)**

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

# Unknown Check completeness Unknown

### **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No