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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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40638

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

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Institution

Opum, Inc Eden Praire, Minnesota

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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

Name of medicine

AIMOVIG

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)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

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

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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