Inpatient Constipation Among Migraine Patients Treated With Preventive Medications: A Retrospective Cohort Study in a United States Electronic Health Record Database

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Study Finalised

Administrative details

EU PAS number

EUPAS37877

Study ID

44534

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective, observational cohort study of migraine patients identified from Optum’s Electronic Health Record (EHR) Research Database from 17 May 2018 through 31 March 2020. Patients over the age of 18, with a clinical diagnosis of migraine, who are treated with erenumab (Aimovig®), other calcitonin-gene related peptide (CGRP) antagonists, or standard of care (SOC) antiepileptic preventive medications, are eligible for this study. The study will describe baseline characteristics, and estimate the incidence proportion of inpatient constipation. The study will also assess the comparability of migraine patients treated with erenumab to migraine patients treated with other CGRP antagonists, and, separately, with SOC antiepileptic preventive medications, with respect to baseline patient characteristics. Finally, if the cohorts are comparable, this study will compare the incidence proportion of inpatient constipation among migraine patients treated with erenumab to migraine patients treated with other CGRP antagonists, and, separately, to migraine patients treated with SOC migraine preventive antiepileptic medications.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Contact details

Study institution contact

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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: 06/12/2019

Actual: 06/12/2019

Study start date

Planned: 11/11/2020

Actual: 18/11/2020

Data analysis start date

Planned: 01/01/2021

Actual: 04/12/2020

Date of final study report

Planned: 01/12/2021

Actual: 01/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS37877-38072.pdf(3.87 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

This retrospective observational study will estimate and compare the incidence proportion of inpatient constipation among migraine patients treated with erenumab, other monoclonal antibodies targeting the CGRP pathway, and SOC antiepileptic preventive medications, to give context to events observed in real-world observations from post-marketing surveillance data.

Study Design

Non-interventional study design

Cohort

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 be drawn from Optum’s EHR database, a de-identified patient-level database that integrates multiple electronic medical record (EMR) data systems with medical claims, prescription, and practice management data.

Study Period

Study cohort members will be identified from 17 May 2018, which is the date of US FDA approval for erenumab, through 31 March 2020. Outcomes will be identified through 31 March 2020.

Inclusion Criteria

Initiators of erenumab, other CGRP antagonists, and SOC preventive medications will be identified during the cohort accrual period using NDCs as recorded in the prescription order table within the EHR database. SOC preventive medications will include select antiepileptic migraine preventive agents. A list of these SOC antiepileptic preventive medications is provided in Section 8.3.1. To select initiator cohorts, only the first prescription order for these medications that are identified during the study period will be assessed for the following criteria:

• At least 18 years of age on the prescription order date

• At least two diagnosis codes for migraine (ICD-10-CM G43.-) on two different days in the 12 months prior to and including the prescription order date, or at

least one prescription order for an acute migraine treatment (triptan or ergot) and at least one diagnosis code for migraine in the 12 months prior to and including the prescription order date

• All cohorts will be required to have at least one outpatient clinical visit at least one year prior to the prescription order date to establish a 12-month baseline period for assessment of prevalent medication use, patient characteristics, and comorbidities. If sample size is a concern, we will also examine the number of patients who have a visit at least 6 and 9 months prior to their prescription order date.

• No prescription order for any CGRP antagonist during the 12-month baseline period.

• For the SOC antiepileptic preventive medication cohort only, no prescription order for any of the five antiepileptic medications during the 12-month baseline period.

The index date will be defined as the date of the earliest prescription order that meets all of the above criteria. Because it is expected that patients will have started erenumab or another CGRP antagonist after attempting treatment with an SOC preventive medication, the SOC antiepileptic preventive medication cohort will be selected from the remaining population of migraine preventive treatment users after the erenumab and CGRP antagonist cohorts are formed. Random sampling may be considered for the SOC antiepileptic preventive medication cohort if the sample size following implementation of the inclusion criteria is much larger than the size of the erenumab and the other CGRP antagonist cohorts.

Exclusion Criteria

Cohort members with missing or conflicting age or sex information will be excluded.

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

Migraine patients

Estimated number of subjects

114828

Study design details

Outcomes

Describe baseline characteristics, estimate the incidence proportion of inpatient constipation, assess the comparability of patients treated with erenumab to patients treated with other CGRP antagonists and to patients treated with SOC antiepileptic preventive medications, and, if appropriate, compare the incidence proportion of inpatient constipation across the three cohorts.

Data analysis plan

Data analyses will include a summary of baseline characteristics and risk factors for constipation, propensity score (PS) matching of the erenumab initiator cohort to the other CGRP antagonists and, separately, to the SOC antiepileptic preventive medication initiator cohorts, and an assessment of the

comparability of the matched cohorts with respect to baseline patient characteristics. The incidence proportion of inpatient constipation and corresponding 95% CIs will be estimated within each cohort. If appropriate, the odds ratio and corresponding 95% confidence intervals will be used to compare the incidence proportion of inpatient constipation across cohorts.

Documents

Study results

20190501_Observational Research Study Report Published Report_Abstract_Redacted.pdf(268.85 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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No