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

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Institution

NoviSci Durham, NC, USA

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/02/2022

Actual: 15/02/2022

Study start date
Planned: 31/03/2022

Actual: 31/03/2022

Data analysis start date
Planned: 01/06/2022

Actual: 09/06/2022

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

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:

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

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

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) ≥1 inpatient claim with a diagnosis of migraine (ICD-10-CM) diagnosis code of G43.xxx).

b) ≥1 outpatient evaluation and management claim with a diagnosis of migraine and a specialty code of 260 (neurologist).

c) ≥1 claim for emergency room visit with a diagnosis of migraine.

d) ≥1 outpatient evaluation and management claim with a diagnosis of migraine PLUS ³1 pharmacy fill for a migraine-specific triptan or an ergotamine class medication within 365 days of each other

e) ≥2 outpatient evaluation and management claims with a diagnosis of migraine between 7 and 365 days apart.

f) ≥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.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Patients with hypertension, myocardial infarction and stroke

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.

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)

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No