Estimating Event Rates Using the Medication Cohort Module: Hypertension and Negative Control Outcomes in New Users of Onabotulinumtoxin A and Monoclonal Antibodies Targeting the Calcitonin-Gene-Related Pathway in the Marketscan EarlyView Claims Database (20200218)

First published: 23/04/2020

Last updated: 19/03/2021

Study Finalised

Administrative details

EU PAS number

EUPAS34832

Study ID

40208

DARWIN EU® study

No

Study countries

United States

Study description

This retrospective observational study will estimate event rates in migraine patients in four medication cohorts in an administrative claims database: new users of erenumab-aooe, new users of fremanezumab-vfrm, new users of galcanezumab-gnlm, and new users of onabotulinumtoxin A. The outcomes of interest include any hypertension, serious hypertension, hypertensive crisis, road traffic accidents, falls, and influenza vaccination.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Last updated: 21/02/2024

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: 17/04/2020

Actual: 17/04/2020

Study start date

Planned: 24/04/2020

Actual: 24/04/2020

Data analysis start date

Planned: 24/04/2020

Actual: 24/04/2020

Date of final study report

Planned: 24/04/2021

Actual: 19/03/2021

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 2020-04-15 English.pdf (628.94 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:

This study will estimate event rates in four medication cohorts in an administrative claims database: new users of erenumab-aooe, new users of fremanezumab-vfrm, new users of galcanezumab-gnlm, and new users of onabotulinumtoxin A. The outcomes of interest include any hypertension, serious hypertension, hypertensive crisis, road traffic accidents, falls, and influenza vaccination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AIMOVIG

Medical condition to be studied

Migraine

Population studied

Short description of the study population

All migraine patients who were 18 years of age on the index date, had one year of continuous enrollment (ie, complete medical and pharmacy coverage) prior to the index date, had a diagnosis of migraine in the year prior to index, and were new users of erenumab-aooe, fremanezumab-vfrm, galcanezumab-gnlm, or onabotulinumtoxin A were eligible to be in the study. Patients were then followed from first use of one of these treatments through 31 January 2020 for the occurrence of any hypertension, serious hypertension, hypertensive crisis, road traffic accidents, falls, and influenza vaccination.

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

30000

Study design details

Outcomes

The outcomes of interest include any hypertension, serious hypertension, hypertensive crisis, road traffic accidents, falls, and influenza vaccination

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Data analysis plan

Event rates based on grouped data will be calculated as the number of events during the follow-up period divided by the total person-time at risk. All event rates will be presented per 1,000 person-years, and CIs for the event rates will be based on the Poisson distribution or approximations of the Poisson distribution for small sample sizes. The outcomes of interest include any hypertension, serious hypertension, hypertensive crisis, road traffic accidents, falls, and influenza vaccination.

Documents

Study results

EUPAS34832-40206.pdf (63.97 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 Truven MarketScan Commercial and Medicare Supplemental databases – Early View 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