A non-interventional study to examine patient characteristics and drug utilization patterns in migraine patients treated with prophylactic drugs in Nordic countries

First published: 29/07/2020

Last updated: 12/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS36014

Study ID

50637

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Norway

Sweden

Study description

The primary objective was to describe utilization of erenumab among patients with migraine.

The secondary objective was to identify potential comparators for a future erenumab PASS.

The exploratory objectives were 1) to estimate rates of cardiovascular outcomes in patients initiating erenumab or other prophylactic migraine medication, and 2) to describe utilization of erenumab and outcome in pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

☐ Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

☐ Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Global Database Studies, IQVIA

☐ Czechia

☐ Finland

☐ Germany

☐ Slovakia

☐ Spain

First published: 17/01/2011

Last updated: 31/07/2024

Institution | Other | ENCePP partner

University of Bergen Kalfarveien 31, 5018 Bergen, Norway

Contact details

Study institution contact

Vera Ehrenstein ve@clin.au.dk

Study contact

ve@clin.au.dk

Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/11/2018

Actual: 06/11/2018

Study start date

Planned: 29/05/2024

Actual: 29/05/2024

Data analysis start date

Planned: 28/08/2024

Actual: 28/08/2024

Date of final study report
Planned: 31/05/2025

Actual: 31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CAMG334A2023-v02-Redacted-Protocol.pdf(1002.23 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objective of this study was to describe utilization of erenumab among patients with migraine

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

AIMOVIG

Study drug International non-proprietary name (INN) or common name

ERENUMAB

Anatomical Therapeutic Chemical (ATC) code

(N02CD01) erenumab

erenumab

Medical condition to be studied

Migraine

Population studied

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

Pregnant women

Estimated number of subjects

10

Study design details

Data analysis plan

All analyses were descriptive. Appropriate summary descriptive statistics were used for categorical and continuous variables.

Cumulative incidences were used to summarize utilization of erenumab.

Rates and cumulative incidences were used to describe the CV endpoints during the follow-up.

Documents

Study report

camg334a2023--legacy-clinical-study-report_Redacted.pdf(1.73 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Pharmacy dispensing records

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