Network meta-analysis of reported adverse events in randomized trials comparing CGRPs for the prophylaxis of episodic migraine

First published: 17/07/2026

Last updated: 17/07/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000874

Study ID

1000000874

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Aaron Jenkins

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/07/2025

Actual: 16/07/2025

Study start date

Planned: 01/07/2026

Date of final study report

Planned: 31/12/2026

Study protocol

C4951096_ Non- Interventional Study Protocol v1.0_25 May2026_Redacted_Highlighted_Redaction completed.pdf (1.06 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Scoping review (including literature review)

Data collection methods:

Secondary use of data

Study design:

The study is a network meta-analysis (NMA) of randomized controlled trials.

Main study objective:

Primary Objectives

1. To compare the relative rates of adverse events from RCTs of the primary outcomes: nausea, constipation & gastrointestinal discomfort/disturbances (as grouped outcome), fatigue & somnolence (as grouped outcome), and hypersensitivity reactions (as grouped outcome) between CGRP-targeted therapies for prophylaxis in EM.
2. To compare the relative rates of adverse events from RCTs of the secondary outcomes: nasopharyngitis, dyspnea, injection site-related AEs (as grouped outcome), and discontinuation (all-cause and due to AEs).

Secondary Objectives

To estimate the incidence (proportion) of various AEs and treatment discontinuation (all cause and due to AEs) from RCTs.

Study drug and medical condition

Medicinal product name

AIMOVIG

EMGALITY

AJOVY

VYEPTI

VYDURA

AQUIPTA

Medicinal product name, other

Rimegepant (Nurtec ODT®/Vydura®)

Atogepant (Qulipta®/Aquipta ®)

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

ERENUMAB

GALCANEZUMAB

FREMANEZUMAB

EPTINEZUMAB

RIMEGEPANT

ATOGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD01) erenumab

erenumab

(N02CD02) galcanezumab

galcanezumab

(N02CD03) fremanezumab

fremanezumab

(N02CD05) eptinezumab

eptinezumab

(N02CD06) rimegepant

rimegepant

(N02CD07) atogepant

atogepant

Population studied

Short description of the study population

The population for this study are adult patients (18 years) with EM enrolled in randomized controlled trials evaluating CGRP-targeted therapies for migraine prophylaxis.

Study design details

Comparators

• Placebo

• Any treatment included in list of interventions

Outcomes

Safety and tolerability outcomes, including (but not limited to):

• Nausea,

• Constipation,

• Gastrointestinal discomfort/disturbances,

• Fatigue,

• Somnolence,

• Hypersensitivity reactions

Hypersensitivity reaction

Anaphylaxis

Angioedema

Hypersensitivity event – rash

Severe rash

Urticaria

Swelling

Oedema

• Nasopharyngitis

• Dyspnea

• Injection site-related AEs

Injection site pain

Injection site erythema

Injection site pruritus

Injection site reaction

Injection site induration

• Discontinuation (all cause), Discontinuation due to AEs

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)

Published literature

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

Unknown