

# DARWIN EU® - CGRP antagonists - Treatment patterns and users characteristics

**First published:** 05/07/2024

**Last updated:** 11/11/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000240

---

### Study ID

1000000240

---

### DARWIN EU® study

Yes

---

### Study countries

- ☐ Croatia
  - ☐ Finland
  - ☐ Germany
  - ☐ Spain
-

## Study description

The aim of this study is to characterise individuals treated with CGRP antagonists for migraine.

The specific study objectives are:

1. Characterisation of patients newly treated with CGRP antagonists (i.e. new user cohort) in terms of demographics, risk factors for erectile dysfunction, insomnia and hypertension and concomitant medications taken at index date. This characterisation will be stratified by sex.
  2. Characterisation of treatment with CGRP antagonists in a cohort of new users in terms of duration of treatment.
  3. Incidence rate of erectile dysfunction, insomnia, and hypertension in a newly diagnosed migraine population (irrespective of treatment) stratified by age groups and sex.
  4. Incidence rate of erectile dysfunction, insomnia, and hypertension in a newly diagnosed migraine population initiating treatment with CGRP antagonists or other prophylactic treatments (anti-epileptics, TCA antidepressants, Beta-blockers, tricyclic antidepressants, calcium channel blockers), stratified by age groups and sex.
  5. Incidence rate of erectile dysfunction, insomnia, and hypertension in the general population (as reference) stratified by age groups and sex.
- 

## Study status

Finalised

## Research institutions and networks

### Institutions

## Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024

**Institution**

**Educational Institution**

**ENCEPP partner**

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- ☐ Belgium
- ☐ Croatia
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Italy
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal

- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

**First published:** 01/02/2024

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

Ilse Schuemie [study@darwin-eu.org](mailto:study@darwin-eu.org)

Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Julieta Politi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 14/05/2024

Actual: 14/05/2024

---

### Study start date

Planned: 02/07/2024

Actual: 02/07/2024

---

### **Date of final study report**

Planned: 13/09/2024

Actual: 30/08/2024

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_D2.2.3\\_Protocol\\_P3-C1-009\\_CGRP antagonists\\_V3.1.pdf](#) (902.68 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Study design:**

Patient-level drug utilisation study.

**Main study objective:**

The aim of this study is to characterise individuals treated with CGRP antagonists for migraine.

The specific study objectives are:

1. Characterisation of patients newly treated with CGRP antagonists (i.e. new user cohort) in terms of demographics, risk factors for erectile dysfunction, insomnia, hypertension, and concomitant medications taken at index date. The characterisation will be stratified by sex.
2. Characterisation of treatment with CGRP antagonists in a cohort of new users in terms of duration of treatment.
3. Incidence rate of erectile dysfunction, insomnia, and hypertension in a newly diagnosed migraine population (irrespective of treatment) stratified by age groups and sex.
4. Incidence rate of erectile dysfunction, insomnia, and hypertension in a newly diagnosed migraine population initiating treatment with CGRP antagonists or other prophylactic treatments (anti-epileptics, TCA antidepressants, Beta-blockers, tricyclic antidepressants, calcium channel blockers), stratified by age

groups and sex.

5. Incidence rate of erectile dysfunction, insomnia, and hypertension in the general population (as reference) stratified by age groups and sex

## Study drug and medical condition

### **Medicinal product name, other**

CGRP antagonists

---

### **Medical condition to be studied**

Migraine

## Population studied

### **Short description of the study population**

- Population of individuals newly initiating first treatment with any of the CGRP antagonists of interest (objectives 1 and 2).
- Population of individuals with newly diagnosed migraine (objectives 3 and 4).
- General population, consisting of all individuals in the database with at least 365 days of database history (objective 5).

## Study design details

### **Setting**

This study will use routinely collected health data from 4 databases in the DARWIN EU® network of data partners from 4 European countries. All databases were previously mapped to the OMOP CDM.

## Documents

## Study report

[DARWIN EU\\_Report\\_P3-C1-009\\_CGRP\\_antagonists\\_V3.pdf](#) (1.47 MB)

## 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)

IQVIA Disease Analyzer Germany

The Valencia Health System Integrated Database

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

### CDM Mappings



**CDM name**

OMOP

---

**CDM website**

<https://www.ohdsi.org/Data-standardization/>

---

## Data quality specifications

**Check conformance**

Unknown

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

---

## Data characterisation

**Data characterisation conducted**

Unknown