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

First published: 05/07/2024

Last updated: 11/11/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000240

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

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Study contact

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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:

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The specific study objectives are:
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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

Name of medicine, 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

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