Post-authorisation Safety Study of Rimegepant in Patients with Migraine and History of Cardiovascular Disease in European Countries

First published: 24/03/2023

Last updated: 03/02/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104168

EU PAS number

EUPAS103990

Study ID

104168

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

As part of the risk management plan for rimegepant in Europe, this post-authorisation safety study (PASS) is being conducted to evaluate whether there is an increased risk of major adverse cardiovascular events (MACE) among patients with migraine and history of cardiovascular disease (CVD) initiating treatment with rimegepant compared with that among patients with migraine, with history of CVD, and being treated with other treatments for migraine, either continuing the current treatment or initiating a new one, other than rimegepant. The study will also describe the use of rimegepant in the initial years after approval in the same population.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Southern Denmark (SDU)

☐ Denmark

First published: 01/02/2024

Last updated: 27/03/2024

Institution | Educational Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

☐ Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joan Forns

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2023

Actual: 01/03/2023

Study start date
Planned: 01/10/2025

Date of final study report
Planned: 01/04/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C4951017_bhv3000-408 protocol v2_17 Nov 2022.pdf(1.29 MB)

C4951017_PROTOCOL- RIMEGEPANT CV PASS_V3.0_26AUG2024.pdf(2.29 MB)

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)

Methodological aspects

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a non-interventional population-based prospective cohort study using a prevalent newuser design.

Main study objective:

The study has 2 primary objectives:
1. To evaluate whether treatment initiation with rimegepant versus treatment with other preventive treatment for migraine (either continuing the current treatment or initiating a new one) increases the risk of MACE in patients with migraine, with history of CVD, and who are being treated with preventive migraine therapies.

2. To evaluate whether treatment initiation with rimegepant versus treatment with other acute treatment for migraine (either continuing the current treatment or initiating a new one) increases the risk of MACE in patients with migraine, with history of CVD, and who are being treated with acute migraine therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Vydura

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

RIMEGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD06) rimegepant

rimegepant

Population studied

Short description of the study population

The study population will include adults with migraine (Protocol Section 9.3.3.1) and history of CVD
(Protocol Section 9.3.3.2) registered in each electronic health care data source who are on treatment
with a qualifying acute or preventive migraine medication (Protocol Table 3) during the study period.

Age groups

Adult and elderly population (≥18 years)

Estimated number of subjects

2500

Study design details

Outcomes

Major adverse cardiovascular event (MACE), Individual components of major adverse cardiovascular event (MACE) including acute myocardial infarction, stroke, coronary heart disease death, cerebrovascular death, coronary bypass surgery, and coronary revascularization.

Data analysis plan

Each research partner will conduct analyses separately within each data source, and results will be pooled via meta-analytic methods, if appropriate.
The analysis will comprise 4 different steps: select the study population, assign exposure and define follow-up, describe the study cohorts and patterns of rimegepant use, and estimate exposure propensity scores. Stabilised propensity score weights will be used in the comparative analyses. Crude and adjusted incidence rates of MACE with their 95% CIs will be estimated using a Poisson regression model with robust estimation of variance. Cumulative incidence of MACE will be estimated using the Kaplan-Meier estimator for each of the 4 exposure groups. Finally, for each comparison, crude and adjusted RRs and risk differences will be estimated using the Kaplan-Meier estimator, and 95% CIs will be derived using bootstrap methods. Adjusted HRs will be estimated with a Cox model.

Documents

Study report

C4951017_PROGRESS REPORT 1_V1.0_09Oct2024.pdf(169.57 KB)

Data management

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Danish registries (access/analysis)

Clinical Practice Research Datalink

PHARMO Data Network

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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