European non-interventional post-authorization safety study related to serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality for romosozumab by the EU-ADR Alliance

First published: 24/09/2020
Last updated: 02/07/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/37810

EU PAS number
EUPAS35881

Study ID
37810

DARWIN EU® study
No

Study countries
Denmark
France
Germany
Italy
Netherlands
Spain
United Kingdom

Study description
The main objective is to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions.

Study status
Ongoing

Research institution and networks

Institutions

UCB Biopharma SRL

Health Search, Italian College of General Practicioners
Italy
First published: 02/03/2010
Last updated 25/06/2014
Institution
Educational Institution
Other
ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS
Germany
First published: 29/03/2010
Last updated 26/02/2024
Institution
Not-for-profit
ENCePP partner

Clinical Practice Research Datalink (CPRD)
United Kingdom
First published: 15/03/2010

Last updated
02/07/2019

Institution

Laboratory/Research/Testing facility

ENCePP partner

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

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

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

Bordeaux PharmacoEpi, University of Bordeaux

France
First published: 07/02/2023
Last updated
08/02/2023

Institution
Educational Institution
Hospital/Clinic/Other health care facility
Not-for-profit
ENCePP partner

Teamit Institute

Spain
First published: 12/03/2024
Last updated
12/03/2024

Institution
ENCePP partner
Other

Networks

EU-ADR Alliance

First published: 01/02/2024
Last updated
01/02/2024

Network

Contact details

Study institution contact

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

Study contact

clinicaltrials@ucb.com
Primary lead investigator

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
30/09/2020
Actual:
30/09/2020

Study start date
Planned:
01/10/2020
Actual:
01/10/2020

Data analysis start date
Planned:
30/09/2026

Date of final study report
Planned:
31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SRL

Study protocol

op0004-protocol-final-Redacted.pdf(1.62 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 type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Main study objective:
The overarching objective of this study is to characterize the risk of serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality including cardiovascular death associated with the use of romosozumab, in comparison with other available osteoporosis medications in routine clinical practice in Europe

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Evenity

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

Anatomical Therapeutic Chemical (ATC) code
(M05BX) Other drugs affecting bone structure and mineralization

Medical condition to be studied
Osteoporosis postmenopausal

Population studied

Age groups
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
337200

Study design details

Outcomes
MACE-2 (first occurrence of death all cause including cardiovascular (CV) death, Myocardial Infarction (MI), or stroke), - Myocardial Infarction (MI)- Stroke- Death due to cardiovascular (CV) causes, ie, MI or stroke- All-cause mortality- First occurrence of death (CV causes), MI, or stroke (MACE-1)

Data analysis plan
Incidence rates and 95 % confidence intervals for each outcome will be calculated for each study drug cohort using a Poisson model. These will be reported for prespecified intervals of 6, 12, 18, and 24 months after treatment indexes, and will be stratified by several factors including age, prior use of osteoporosis medication, and previous history of cardiovascular event. For comparative safety studies, propensity score matching will be used to match patients using romosozumab to up to 3 users of alendronate. Cox regression models stratified by matched sets will be used to calculate hazard ratios and 95 % CIs for each of the safety endpoints (MI, stroke, MACE-1, and MACE-2) according to drug exposure in the propensity-matched cohorts. The pooled estimates of the incidence rate for the databases will be calculated using the random or fixed effects meta-analysis depending on heterogeneity detected using an I^2 threshold of >40 %.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink
Danish registries (access/analysis)
IPCI
The Information System for Research in Primary Care (SIDIAP)
German Pharmacoepidemiological Research Database
Système National des Données de Santé (French national health system main database)

Data source(s), other
Health Search Database (HSD), Italy

Data sources (types)
Administrative data (e.g. claims)
Electronic healthcare records (EHR)

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