EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO ADHERENCE TO THE RISK MINIMIZATION MEASURES FOR ROMOSOZUMAB BY THE EU-ADR ALLIANCE

First published: 24/09/2020

Last updated: 17/06/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS35956

Study ID

37813

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

To study the adherence to the risk minimization measures in the product information by estimating the compliance with contraindications and target indication amongst incident romosozumab users, and analyzing the utilization patterns.

Study status

Ongoing

Research institutions and networks

Institutions

UCB Biopharma SRL

Health Search, Italian College of General Practicioners

- [ ] Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

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: 17/01/2025

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: 23/05/2025

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 | Other | ENCePP partner

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. clinicaltrials@ucb.com

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

op0005-protocol-final-Redacted.pdf (1.18 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:
To study the adherence to the risk minimization measures in the product information by estimating the compliance with contraindications and target indication amongst incident romosozumab users, and analyzing the utilization patterns.

Study drug and medical condition

Name of medicine
EVENITY

Medical condition to be studied
Osteoporosis postmenopausal

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
1000

Study design details

Outcomes

Prevalence of contraindications amongst new romosozumab users, - Prevalence of documented indication amongst new romosozumab users- Monthly prevalence of use for each osteoporosis drug- Monthly incidence of use for each osteoporosis drug- Overall duration of treatment/persistence- Proportion persistent at 6, 12, 18, and 24 months- number and percentage of patients who switch to another osteoporosis medication

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Data analysis plan

All measures of primary and secondary outcomes will be calculated for each of the contributing databases separately. Estimates will be provided overall (for the whole source population) and stratified by sex (except for use in men), age (5-year bands) and calendar year. Baseline characteristics of all users of romosozumab and of other osteoporosis medications, as well as of romosozumab users in each of the contraindication and restriction of indication groups, will be described.

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)

Clinical Practice Research Datalink

Danish registries (access/analysis)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (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