

# EUROPEAN NON-INTERVENTIONAL POST AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSUZUMAB BY THE EU ADR ALLIANCE

**First published:** 24/09/2020

**Last updated:** 17/02/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36005

---

### Study ID

37816

---

### DARWIN EU® study

No

---

### Study countries

Denmark

France

Germany

- Italy
  - Netherlands
  - Spain
  - United Kingdom
- 

### **Study description**

The overarching objective of this study is to monitor the potential risk of serious infection associated with the use of romosozumab in comparison with other available osteoporosis medications in routine clinical practice in Europe.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

[UCB Biopharma SRL](#)

## Contact details

### **Study institution contact**

Clinical Trial Registries and Results [clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

[Study contact](#)

[clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

### **Primary lead investigator**

# Clinical Trial Registries and Results

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 30/09/2020

---

### **Study start date**

Actual: 01/10/2020

---

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

Actual: 10/12/2025

## Sources of funding

### More details on funding

UCB Biopharma SRL

## Study protocol

[op0006-protocol-final-Redacted.pdf](#) (1.36 MB)

[OP0006-Protocol Substantial Amendment 4\\_Redacted.pdf](#) (1.5 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)

**Other study registration identification numbers and links**

OP0006

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Disease /health condition

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

**Study design:**

This will be a multi-national, multi-database cohort study of new users of romosozumab and new users of other OP medications. The study period is expected to last for 4 years (2020 to 2024).

**Main study objective:**

The overarching objective of this study is to monitor the potential risk of serious infection (SI) associated with the use of romosozumab in comparison with other available osteoporosis (OP) medications in routine clinical practice in Europe.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

[EVENTY](#)

---

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

ROMOSUZUMAB

ALENDRONIC ACID

IBANDRONIC ACID

RISEDRONATE SODIUM

DENOSUMAB

TERIPARATIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(M05BX06) romosozumab

romosozumab

(M05BA04) alendronic acid

alendronic acid

(M05BA06) ibandronic acid

ibandronic acid

(M05BA07) risedronic acid

risedronic acid

(M05BA08) zoledronic acid

zoledronic acid

(M05BA06) ibandronic acid

ibandronic acid

(M05BX04) denosumab

denosumab

(H05AA02) teriparatide

teriparatide

---

**Medical condition to be studied**

Osteoporosis postmenopausal

Infection

COVID-19

## Population studied

**Short description of the study population**

The study population will comprise of all women from the 7 participating data sources with severe OP who are dispensed or prescribed an OP medication of interest for the first time (new user) during the study period, have been continuously registered in the data source for at least 12 months prior to the first recorded dispensing/prescription of the OP medication of interest, and are at least 50 years of age on the date of the first dispensing/prescription of the OP medication of interest. Women with a diagnosis of cancer (any except basal cell skin cancer) or Paget disease at any time before treatment initiation will be excluded.

---

### **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**

328256

## **Study design details**

### **Setting**

Participants from 7 European countries, including North, South and Central Europe, will be included. Data from primary care, secondary care, health registers, prescription/dispensation registers and claims will be utilized.

---

### **Comparators**

Alendronate (ATC M05BA04) will be the active comparator in the comparative safety analyses (Objective 3).

---

## Outcomes

Serious infection (SI) leading to hospitalization, Death due to Serious infection (SI), operationalized as either of:- In-hospital death with a diagnosis of infection during the same admission/episode- Recorded diagnosis of any infection followed by death in the subsequent month

---

## Data analysis plan

Incidence rates and 95 % confidence intervals (CIs) for Serious Infection (SI) events 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 key SI risk factors. 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 (SI leading to hospitalization and SI leading to death) 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  $>40\%$ .

## Documents

### Study results

[OP0006-Final Study Report\\_Redacted.pdf](#) (1.91 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)**

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