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

First published: 24/09/2020

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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

Study contact

clinicaltrials@ucb.com

Primary lead investigator

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:

Secondary use of data

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

EVENITY

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

ROMOSOZUMAB

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

328.256

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

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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