Clinical Characteristics, Including History of MI and Stroke, Among US Post-menopausal Women Initiating Treatment With Romosozumab and Other Anti-osteoporosis Therapies (20190205)

First published: 14/09/2020

Last updated: 12/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS37160

Study ID

37633

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective, repeated analysis design study. Post-menopausal women, aged 55 and above, who have initiated treatment with romosozumab or other anti-osteoporosis medications, will be included in this study.
The planned study period is approximately 5 years, made up of four 1-year blocks, one 6-month block and a 6-7 month estimated data-lag.
Information will be collected to evaluate the clinical characteristics and pharmacovigilance of romosozumab and other anti-osteoporosis medications in post-menopausal women in the United States.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Networks

PCORnet Clinical Data Research Network (CDRN)

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2020

Actual: 03/09/2020

Study start date

Planned: 15/09/2020

Actual: 15/09/2020

Data analysis start date

Planned: 28/02/2025

Actual: 16/12/2024

Date of final study report

Planned: 28/02/2026

Actual: 13/02/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

Protocol-Published Amendment romosozumab 20190205 1 (2).pdf(1.43 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

Protocol number - 20190205

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Characterize patients baseline clinical characteristics

Main study objective:

This study is designed to fulfil US FDA post-marketing requirements

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, repeated analysis design

Study drug and medical condition

Name of medicine

EVENITY

Name of medicine, other

Zolendronic acid

Oral bisphosphonates

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

ABALOPARATIDE

ALENDRONIC ACID

DENOSUMAB

ROMOSOZUMAB

TERIPARATIDE

Anatomical Therapeutic Chemical (ATC) code

(H05AA02) teriparatide

teriparatide

(H05AA04) abaloparatide

abaloparatide

(M05BX04) denosumab

denosumab

(M05BX06) romosozumab

romosozumab

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)

Special population of interest

Other

Special population of interest, other

Post-menopausal women

Estimated number of subjects

122259

Study design details

Outcomes

Describe demographic and clinical characteristics, including history of cardiovascular disease (e.g., MI, stroke), cardiovascular risk factors, osteoporotic fracture, risk factors for osteoporosis and osteoporotic fracture, other comorbidities, concomitant medication use, and healthcare utilization all available historical data preceding initiation of romosozumab or other anti-osteoporosis medication, Repeat primary objective analyses in secondary datasets (Medicare claims linked to PCORnet Clinical Data Research Network (CDRN) data, and Optum claims – Optum EHR linked dataset).

Data analysis plan

All planned statistical analyses are descriptive, no hypothesis testing will be conducted.

All study objectives for the primary analysis will be assessed separately in each primary data source, i.e., FFS Medicare and Optum CDM claims data.

Categorical variables will be presented in tabular form as number and

percentage, continuous variables will be presented as number, mean with standard deviation, and median with interquartile range.
Differences in clinical characteristics will be described in four pairwise exposure groups:
1) romosozumab vs. denosumab,
2) romosozumab vs. PTH analog (teriparatide or abaloparatide),
3) romosozumab vs. zolendronate,
4) romosozumab vs. oral BPs. Standardized mean difference (SMD) will be used to characterize differences between exposure groups.

Documents

Study report

20190205_ORSR_abstract_Redacted.pdf(861.9 KB)

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), other

Primary Datasets

1) Fee-for-service Medicare administrative claims data

2) Optum Clinformatics® Data Mart [CDM] claims data

Secondary Datasets

1) PCORnet Clinical Data Research Network (CDRN)

2) Optum EHR

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