The Incidence and Risk factors for Hypocalcaemia Among Osteoporosis Patients Receiving Romosozumab or Other Antiresorptive Therapy in Japan -- A Retrospective Cohort Study Within the Medical Information Database Network (20190207) (MID-NET)

First published: 25/03/2024

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000055

Study ID

1000000055

DARWIN EU® study

No

Study countries

Japan

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Networks

Medical Information Database Network (MID-NET)

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: 16/05/2024

Actual: 07/06/2024

Study start date

Planned: 30/04/2026

Actual: 28/05/2026

Data analysis start date

Planned: 30/04/2026

Actual: 28/05/2026

Date of final study report

Planned: 07/04/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen 100%

Study protocol

Protocol-Published Amendment romosozumab 20190207 2 .pdf (787.84 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

20190207

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study within the Medical Information Database Network

Main study objective:

The primary objective is to evaluate the risk of hypocalcaemia in participants receiving romosozumab relative to those receiving other antiresorptive treatments, broken down by the presence of potential risk factors for hypocalcaemia including renal impairment and others at follow-up initiation.

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

Anatomical Therapeutic Chemical (ATC) code

(M05BX06) romosozumab

romosozumab

Additional medical condition(s)

Hypocalcaemia

Population studied

Short description of the study population

The target populations will include osteoporosis patients treated with romosozumab or active comparators, namely antiresorptive therapies known to increase the risk of hypocalcaemia (denosumab, bisphosphonates, and selective estrogen receptor modulators [SERMs]).

Age groups

- Adults (18 to < 65 years)
  - 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)

Special population of interest

Renal impaired

Special population of interest, other

4,200 romosozumab users; 30,069 active comparator users

Estimated number of subjects

34.269

Study design details

Setting

Japanese routine clinical setting

Comparators

Control group: either of the antiresorptive drugs described below:
(1) Denosumab
(2) Bisphosphonates (alendronate sodium hydrate, zoledronic acid hydrate, minodronic acid hydrate, sodium risedronate hydrate, ibandronate sodium hydrate)
(3) SERM (raloxifene hydrochloride)

Outcomes

The corrected serum calcium level specified in the Criteria for Seriousness Classification of Adverse Drug Reactions (SD Notification No. 80)4) was used for the definition of hypocalcaemia. The calculation method for corrected serum calcium levels is described in "8.7.2.3 Handling of Processing Variables

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

The data used in this study will be extracted from the MID-NET system. MID-NET is constructed and operated by PMDA for the purpose of evaluating the safety of drugs and other medical treatments mainly based on the regulatory requirements using electronic medical care information in the database. MID-NET contains the standardized and coded data of electronic medical records, medical insurance claims data, and DPC data including laboratory values obtained in 2009 or later from more than 5 million patients. The data are provided by 23 hospitals from 10 healthcare organizations (as of December 2021), mainly university hospitals.

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

Unknown