

# 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

Planned

## Administrative details

### EU PAS number

EUPAS1000000055

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### Study ID

1000000055


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### DARWIN EU® study

No

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## Study countries

 Japan

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## Study status

Planned

## 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](mailto: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

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**Study start date**

Planned: 30/04/2026

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**Data analysis start date**

Planned: 30/04/2026

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**Date of final study report**

Planned: 30/09/2026

## 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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](#)

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

ROMOSOZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(M05BX06) romosozumab

romosozumab

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**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]).

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**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)
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**Special population of interest**

Renal impaired

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**Special population of interest, other**

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

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### **Estimated number of subjects**

34269

## 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.

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown