# A Real-world, Prospective, Observational Study of Prolia® (20180401)

**First published:** 13/04/2023

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS37579

**Study ID**

105188

**DARWIN EU® study**

No

**Study countries**

☐ China

**Study description**

This is a real-world, prospective, single arm, observational multi-center study. At least 3000 women with postmenopausal osteoporosis (PMO) who are being prescribed Prolia® will be enrolled.

The planned study period is 3 years. Information will be collected to evaluate the safety and effectiveness of Prolia® in a post-marketing setting in China. All data collected for this study will be extracted from the information generated or gathered through routine medical practice.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Amgen

United States

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**Institution**

# 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: 19/08/2020

**Study start date**
Planned: 31/05/2023

Actual: 22/05/2023

**Data analysis start date**
Planned: 24/04/2026

**Date of final study report**
Planned: 15/10/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

Protocol-Published Original denosumab 20180401 .pdf (2.02 MB)

## 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

Protocol number - 20180401

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To assess the safety of Prolia® in PMO subjects according to the China Prescribing Information in a post-marketing setting.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Real-world, observational, multi-center study

## Study drug and medical condition

**Medicinal product name**

PROLIA

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

DENOSUMAB

**Anatomical Therapeutic Chemical (ATC) code**

(M05BX04) denosumab

denosumab

**Medical condition to be studied**

Osteoporosis postmenopausal

**Additional medical condition(s)**

Postmenopausal Osteoporosis (PMO)

## Population studied

**Short description of the study population**

The study population comprises patients treated with Prolia in a clinical setting which includes any primary through tertiary healthcare setting where Prolia is prescribed.

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**Age groups**

- 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**

Hepatic impaired

Immunocompromised

Renal impaired

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**Estimated number of subjects**

3000

## Study design details

**Outcomes**

The primary outcomes are to estimate the incidence rates of adverse events, serious adverse events, and ADRs among postmenopausal subjects receiving Prolia® according to the China Prescribing Information (PI) in a post-marketing setting.

The secondary outcomes of the study are: percent change from baseline in BMD

of the lumbar spine and/or total hip and/or femoral neck.
Incidence of clinical fractures during the treatment with Prolia® characteristics of subjects receiving Prolia® in the post-marketing setting.

**Data analysis plan**

Descriptive analysis of the collected safety and effectiveness endpoints will be conducted. No hypothesis testing will be performed.
Categorical outcomes will be summarized by the number and percentage of subjects in each category.
Continuous outcomes will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles, and minimum and maximum values.
For the incidence, 95% CI will be presented based on an exact method.

# 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 sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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