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

First published: 13/04/2023

Last updated: 13/06/2025

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

First published: 01/02/2024

Last updated: 21/02/2024

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

Name of medicine

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.

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)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

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