

# Prolia® persistence in post-menopausal women with osteoporosis, over 70 years, at increased risk of fracture, treated in routine clinical practice in Bulgaria

**First published:** 26/05/2017

**Last updated:** 20/10/2020

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19156

---

### Study ID

37686


---

### DARWIN EU® study

No

---

### Study countries

 Bulgaria

---

### Study description

The purpose of this study is to estimate persistence with Prolia® in Prolia® treated at increased risk of fracture postmenopausal women, aged >70 years, at 12, 18 and 24 months in real life clinical practice in Bulgaria. Objective is to estimate the proportion of patient at increased risk of fracture on Prolia® treatment for 2 years. Demographic and clinical characteristics in -increased risk of fracture women >70 years with osteoporosis and treated with Prolia® will be described.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Amgen



United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

Institution

Multiple centres: 14 centres are involved in the study

## 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: 22/03/2017

Actual: 22/03/2017

---

**Study start date**

Planned: 14/07/2017

Actual: 11/07/2017

---

**Data analysis start date**

Planned: 30/11/2019

Actual: 07/11/2019

---

**Date of final study report**

Planned: 20/10/2020

Actual: 20/10/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol Summary.pdf](#) (208.57 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Persistence to treatment in women at increased risk of fracture

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To estimate persistence with Prolia® in Prolia treated post-menopausal women with osteoporosis, aged >70 years, at increased risk of fracture, at 12, 18 and 24 months in real life clinical practice in Bulgaria.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

National retrospective and prospective observational study based on clinical data of PMO women at increased risk of fracture receiving treatment with Prolia® for osteoporosis in routine clinical practice in Bulgaria.

## Study drug and medical condition

## Medicinal product name

PROLIA

---

## Medical condition to be studied

Osteoporosis postmenopausal

## Population studied

### Short description of the study population

Postmenopausal women > 70 years at increased risk of fracture, with/without previous fracture in real life clinical practice referred by orthopedic, neurology or other clinical outpatients and hospital settings to endocrinology and rheumatology centers to be diagnosed with osteoporosis and treated with Prolia® as per specialist's decision will be included in the study.

Inclusion criteria:

- Women with osteoporosis >70 years old, referred to endocrinologists or rheumatologists by orthopedic, neurology or other clinics/outpatient practices – to be diagnosed with Dual energy X-ray absorptiometry (DXA) and treated with Prolia®
- The patient - meeting FRAX criteria for high risk: either  $\geq 3\%$  risk for hip fracture or  $\geq 20\%$  for major osteoporotic fracture
- The patient has received at least 1 Prolia® injection prior to approval of the study by Bulgarian Regulatory Agency and Bulgarian Central Ethics Commission. The date of the approval comes into force when Amgen has been handed the written decisions.

Exclusion criteria:

- Participation in clinical or device trials in the last 6 months
- Patient is currently participating or has participated in Prolia® clinical trials

- Patient is on other anti-osteoporosis medication at the time of enrolment (e.g. oral/i.v. bisphosphonates, or anabolics). Vitamin D and Calcium supplementation are not considered as osteoporosis medication and therefore are permitted.

---

### **Age groups**

- 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**

Osteoporosis patients

---

### **Estimated number of subjects**

250

## Study design details

### **Outcomes**

Persistence to Prolia®, time to non-persistence/discontinuation, -Age, age at menopause, prior fragility fracture, prior PMO therapy, history of treatment discontinuation of osteoporosis therapy, FRAX at baseline, -Number of injections received per patient at the end of the study and after 12, 18 and 24 months - Changes from baseline in BMD T-score

---

### **Data analysis plan**

Baseline characteristics will be summarized using descriptive statistics. Counts and percentages will be provided for categorical outcomes. 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.

## Documents

### Study results

[EUPAS19156-37684.pdf](#) (302.63 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 sources (types)

[Other](#)

---

### Data sources (types), other

Medical records

## 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