

# The use, safety, and effectiveness of Prolia in clinical practice among Chinese women with post-menopausal osteoporosis – Taiwan and Hong Kong (20180325)

**First published:** 12/11/2018

**Last updated:** 28/09/2020

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/37411>

### EU PAS number

EUPAS26372

### Study ID

37411

### DARWIN EU® study

No

## Study countries

☐ Hong Kong

☐ Taiwan

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## Study description

Among Chinese women being treated in clinical practice for post-menopausal osteoporosis, the objectives are to describe the use of denosumab, characterize the safety of denosumab, and to evaluate the effectiveness of denosumab for the reduction of clinical osteoporotic fractures.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Amgen

☐ United States

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

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**Institution**

National Cheng Kung University, Tainan School of pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, The University of Hong

Kong, Hong Kong Centre for Safe Medication  
Practice and Research, Department of  
Pharmacology and Pharmacy, Li Ka Shing Faculty  
of Medicine

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

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: 01/08/2018

Actual: 01/08/2018

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### Study start date

Planned: 21/01/2019

Actual: 21/01/2019

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**Data analysis start date**

Planned: 21/01/2019

Actual: 21/01/2019

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**Date of final study report**

Planned: 01/08/2020

Actual: 28/09/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20180325\\_01.02.06 Public Redacted Protocol Ver 1.0 2019-01-02 English.pdf](#)  
(609.09 KB)

## Regulatory

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

No

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Among Chinese women being treated in clinical practice for post-menopausal osteoporosis, the objectives are to:1. Describe the use of denosumab and the patient characteristics2. Characterize the safety of denosumab 3. Evaluate the effectiveness of denosumab for the reduction of clinical osteoporotic fractures

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

PROLIA

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## **Medical condition to be studied**

Osteoporosis

## **Population studied**

### **Short description of the study population**

The study population includes women aged 55 years or older (i.e., postmenopausal) who received at least one dose of Prolia. To ensure that included women are receiving Prolia for the indication of PMO, all are excluded with a history of Paget's disease or malignancy. To be representative of all patients being treated with Prolia in clinical practice, there are no other exclusion criteria.

#### **Inclusion Criteria**

- Use of Prolia in clinical practice
- Complete data available on age and sex

#### **Exclusion Criteria**

- Males
  - Less than 55 years old at initial use of Prolia
  - History of any malignancy within 1 year before initial use of Prolia
  - History of Paget's disease within 1 year before initial use of Prolia
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### **Age groups**

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**

Other

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## **Special population of interest, other**

Osteoporosis patients

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## **Estimated number of subjects**

40000

# Study design details

## **Data analysis plan**

Risk estimation

# Documents

## **Study results**

[01.42.03\\_csr-20180325-observational research study report- abstract\\_public-redacted.pdf](#)(1.05 MB)

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## Data management

# Data sources

## **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

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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**

No