# The Safety and Clinical Effectiveness of Denosumab Among Chinese Men With Osteoporosis – a Real World Study in Taiwan (20210040)

**First published:** 14/01/2022

**Last updated:** 09/06/2022

Study Finalised

## Administrative details

**EU PAS number**

EUPAS45083

**Study ID**

47635

**DARWIN EU® study**

No

**Study countries**

☐ Taiwan

**Study status**

Finalised

## 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: 18/10/2021

Actual: 18/10/2021

**Study start date**
Planned: 14/01/2022

Actual: 18/01/2022

**Data analysis start date**
Planned: 14/01/2022

Actual: 18/01/2022

**Date of final study report**
Planned: 14/01/2023

Actual: 22/04/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

EUPAS45083-45417.pdf(1.8 MB)

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

This real-world study of the clinical practice of Taiwan aims to characterize the safety and evaluate the effectiveness of Prolia among Chinese men with osteoporosis.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

DENOSUMAB

---

**Medical condition to be studied**

Osteoporosis

## Population studied

**Short description of the study population**

The study population includes men aged 50 years or older who received at least one dose of Prolia. To ensure that included men who were receiving Prolia for the indication of MOP, all with a history of Paget’s disease or malignancy are excluded.

Inclusion Criteria

1. Men ( ≥ 50 years old) in Taiwan’s Health Insurance Research Database
2. Receipt of at least 1 administration of denosumab
3. Complete age and gender information

Exclusion Criteria

1. History of any malignancy within 1 year before initial use of Prolia
2. History of Paget’s disease within 1 year before initial use of Prolia

---

**Age groups**

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

**Estimated number of subjects**

16000

## Study design details

**Outcomes**

Effectiveness outcome: hip fracture, Safety outcomes: osteonecrosis of the jaw, atypical femur fracture, hypocalcemia, Clinical vertebral fracture, Non-vertebral fracture (hip, wrist, forearm, humerus), Major osteoporotic fracture (clinical vertebral, hip, wrist, forearm, humerus)

**Data analysis plan**

This study includes both a descriptive analysis for safety endpoints and a comparative analysis for effectiveness endpoints.

## Documents

**Study results**

20210040 ORSR Abstract 04May2022_Redacted.pdf(305.79 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 source(s), other**

Health Insurance Research Database (HIRD) of the Taiwan Bureau of Health Insurance Taiwan

**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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No