

# Denosumab Global Safety Assessment in Multiple Observational Databases (20090522)

**First published:** 31/01/2019

**Last updated:** 15/11/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/38617>

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### EU PAS number

EUPAS27559

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### Study ID

38617

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### DARWIN EU® study

No

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### Study countries

Denmark

- Norway
  - Sweden
  - United States
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### Study description

This is a prospective open-cohort study with annual assessment and reporting of descriptive findings from 5 secondary data sources. The study period will include up to 10 years in each data system.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Amgen

- United States

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

**Last updated:** 21/02/2024

**Institution**

#### Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

- Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## Aarhus University Hospital

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

**Last updated:** 01/02/2024

**Institution**

University of Optum Insight USA, University of  
Alabama at Birmingham USA

## 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.

## Study timelines

### **Date when funding contract was signed**

Actual: 30/12/2009

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### **Study start date**

Actual: 26/05/2010

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### **Data analysis start date**

Planned: 20/10/2023

Actual: 01/04/2023

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### **Date of interim report, if expected**

Planned: 26/11/2019

Actual: 15/05/2019

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### **Date of final study report**

Planned: 21/08/2024

Actual: 13/07/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

NCT02520362

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

Determine incidence rates of adverse events of special interest (AESI) in patients exposed to denosumab, patients exposed to bisphosphonates, and among all women with PMO.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

This is a prospective open-cohort study with annual assessment and reporting of descriptive findings from 5 secondary data sources.

## Study drug and medical condition

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

DENOSUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(M05BX04) denosumab

denosumab

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**Medical condition to be studied**

Osteoporosis

## Population studied

## **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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## **Estimated number of subjects**

517991

# Study design details

## **Outcomes**

Incidence rates of AESI (per 100,000 Person-years) will be assessed in patients exposed to denosumab, patients exposed to biphosphonates, and among all women with PMO

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## **Data analysis plan**

Descriptive statistics will be used to characterize exposure cohorts with respect to patient characteristics, clinical features, and AESI risk factors. Person-year adjusted AESI incidence rates will be calculated among exposure cohorts. Exploratory analyses comparing incidence rates of AESI in women with PMO adjusting for potential confounders will also be conducted. Descriptive statistics will be used to characterize denosumab utilization patterns. Descriptive statistics will be used to characterize patients receiving Prolia for unapproved indications.

# Documents

## **Study results**

## Data management

### Data sources

#### **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

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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