

# Occurrence of serious infection among patients with rheumatoid arthritis or psoriatic arthritis concurrently exposed to an immunosuppressive biologic and denosumab: US physician practice chart review study (20150207)

**First published:** 01/12/2015

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11662

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### Study ID

20935

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### DARWIN EU® study

No

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### Study countries

### **Study description**

This study will be conducted to describe the occurrence of serious infections in patients with rheumatoid arthritis or psoriatic arthritis who are concurrently treated with an immunosuppressive biologic and denosumab at two rheumatology clinics in the United States.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[ICON Clinical Research \(Canada\)](#)

[Multiple centres: 2 centres are involved in the study](#)

## Contact details

### **Study institution contact**

Global Development Leader Amgen Inc.  
[medinfo@amgen.com](mailto: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

Actual: 10/04/2015

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### Study start date

Planned: 07/12/2015

Actual: 20/02/2016

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### Data analysis start date

Planned: 31/07/2016

Actual: 13/09/2016

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### Date of final study report

Planned: 13/09/2017

Actual: 11/09/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen, Inc

## Study protocol

[Amgen Prolia Protocol ORRG postreview V7.0.pdf](#) (286.31 KB)

[Amgen Prolia Protocol V2.0 \(amendment\) clean \(10\).pdf](#) (609.32 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:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

Occurrence of serious infection in patients concurrently exposed to denosumab treatment for osteoporosis and immunosuppressive biologic medications for treatment of rheumatoid arthritis and psoriatic arthritis.

**Data collection methods:**

Secondary use of data

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**Main study objective:**

This study will be conducted to describe the occurrence of serious infections in patients with rheumatoid arthritis or psoriatic arthritis who are concurrently treated with an immunosuppressive biologic and denosumab at two rheumatology clinics in the United States.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective chart review

## Study drug and medical condition

**Medicinal product name**

PROLIA

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## **Anatomical Therapeutic Chemical (ATC) code**

(M05BX04) denosumab

denosumab

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## **Medical condition to be studied**

Rheumatoid arthritis

Psoriatic arthropathy

## **Population studied**

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

Patients with Rheumatoid arthritis (RA) and Psoriatic arthropathy (PsA) who are using an immunosuppressive biologic and denosumab concurrently and are -

- Administered at least one dose of denosumab prior to 18 March 2015 and during use of immunosuppressive biologic (date of initiating denosumab marks the index date)
  - Administered at least one dose of an immunosuppressive RA or PsA biologic agent during the pre-index period
  - Received care at one of the two participating clinics before and after denosumab initiation
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### **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)
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### **Special population of interest**

### **Estimated number of subjects**

150

## Study design details

### **Outcomes**

The primary outcome is the occurrence of serious infection, defined as infection requiring hospitalization and/or intravenous antibiotics.

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### **Data analysis plan**

Descriptive analyses include assessment of cumulative incidence/percent of patients with serious infection, number of serious infection episodes (events), and incidence rate of serious infection before and up to 12 months after treatment initiation. Infection rate will be the total number of serious infection events divided by the sum of patient-time at risk.

## Documents

### **Study results**

[Abstract from 01.09.01 Clinical Study Report 2017-08-29 20150207 Final r....pdf](#)  
(125.68 KB)

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## 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](#)

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### Data sources (types), other

Medical chart review

## 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**

Unknown