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

Study ID

20935

DARWIN EU® study

No

Study countries

United States

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.

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

Study contact

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

Study start date

Planned: 07/12/2015

Actual: 20/02/2016

Data analysis start date

Planned: 31/07/2016

Actual: 13/09/2016

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

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

Study type:

Non-interventional study

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

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

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medicinal product name

PROLIA

Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

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)

Special population of interest

Immunocompromised

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.

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)

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 chart review

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

Unknown