Burden of serious infection in patients with rheumatoid arthritis treated with Prolia ovserved in a clinical setting (20140127)

First published: 18/12/2014

Last updated: 10/09/2016

Study Finalised

Administrative details

EU PAS number

EUPAS8054

Study ID

15158

DARWIN EU® study

No

Study countries

☐ Canada

Study description

This is a retrospective observational study to describe the occurrence of serious infection in RA patients in a Canadian medical practice treated concomitantly with both an immunosuppressive biologic agent and Prolia.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Amgen

Contact details

Study institution contact

Global Development Leader Amgen, Inc
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Study contact

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Primary lead investigator

Global Development Leader Amgen, Inc

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/02/2014

Study start date

Planned: 08/12/2014

Actual: 05/01/2015

Data analysis start date

Actual: 10/09/2015

Date of final study report

Planned: 15/04/2016

Actual: 09/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20140127 Protocol Ver 1.0 2014-09-30 English.pdf (483.37 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Descriptive Study

Data collection methods:

Secondary use of data

Main study objective:

Estimate frequency of serious infections among patients on immunosuppressive biolologic RA treatment and Prolia.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medicinal product name

PROLIA

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

The study population will be derived from a source population of adult patients with rheumatoid arthritis and osteoporosis who were receiving medical care at the Hamilton Rheumatology medical practice in Ontario, Canada, between 01 July 2010 and 31 July 2014. Inclusion criteria: Men and women ≥ 18 years old with a diagnosis of rheumatoid arthritis registered in the Hamilton Rheumatology medical practice at least 3 months before and 3 months after index date who had received at least one injection, infusion or filled a prescription for an immunosuppressive biologic therapy for RA during the study period with Pharmaca Health.

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

1200

Study design details

Outcomes

serious infections, opportunistic infections

Data analysis plan

Descriptive statistics will be used to describe patient characteristics in the biologics and Prolia-exposed and Prolia-unexposed patients. Mean and standard deviation, median and range will be reported for continuous variables, and frequency distributions will be reported for categorical variables. Cumulative incidence of infection (incidence proportion) in RA patients treated concomitantly with an immunosuppressive biologic and Prolia will be assessed separately over a 6 and 12-month follow up period. The incidence rate is calculated as the total number of patients with an infection divided by the summation of patient-days of applicable time at risk from all patients, where the time at risk is censored at the first occurrence of the event for patients experiencing an infection. To provide context to the findings, we will also describe the infection experience in RA patients treated with an immunosuppressive biologic agent (Prolia unexposed).

Documents

Study results

01.09.01 Clinical Study Report Abstract 2016-09-01 20140127 Final report.pdf (133.2 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

Hamilton rheumatology medical practice EMR database

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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