An Active Surveillance, Post Authorization Safety Study (PASS) to Estimate Incidence Rates of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Interest among all Patients Treated with Ruxience for Rheumatoid Arthritis (RA) within the Swedish, Population based, Anti Rheumatic Treatment in Sweden (ARTIS) Register

First published: 21/10/2020

Last updated: 16/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37694

Study ID

41897

DARWIN EU® study

No

Study countries

Sweden

Study description

To estimate incidence rates of infections, including serious infections, malignancies, cardiovascular events, and use during pregnancy among patients with rheumatoid arthritis in the ARTIS register who initiate Ruxience.

Study status

Finalised

Research institutions and networks

Institutions

Karolinska Institutet

Sweden

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Department of Rheumatology, Karolinska University Hosptial

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cynthia de Luise

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/10/2020

Study start date

Planned: 01/07/2021

Actual: 01/07/2021

Data analysis start date

Planned: 31/12/2023

Date of final study report

Planned: 30/11/2024

Actual: 17/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

B3281013_PROTOCOL AND APPROVAL_ARTIS PASS_Ruxience_V1.0_14OCT2020.pdf (5.63 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

To estimate incidence rates of infections, including serious infections, malignancies, cardiovascular events, use during pregnancy among patients with rheumatoid arthritis in the ARTIS register who initiate Ruxience.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

RUXIENCE

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

RITUXIMAB

Anatomical Therapeutic Chemical (ATC) code

(L01XC02) rituximab

rituximab

Medical condition to be studied

Rheumatoid arthritis

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

75

Study design details

Data analysis plan

Descriptive summaries of Ruxience exposed patients and crude incidence rates and 95% confidence intervals of safety event of interest.

Documents

Study report

B3281013 ARTIS Final Study Report Abstract 17JUL2024.pdf (134.42 KB)

B3281013 ARTIS Final Study Report 17JUL2024.pdf (287.42 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)

Disease registry

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