Retrospective Post-Marketing Safety Surveillance Study of Tofacitinib in Psoriatic Arthritis (PsA) and Rheumatoid Arthritis (RA)

First published: 21/09/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50422

EU PAS number

EUPAS46286

Study ID

50422

DARWIN EU® study

No

Study countries

Canada

Study description

To describe the demographics and clinical characteristics of Psoriatic Arthritis or Rheumatoid Arthritis patients treated with tofacitinib for whom adverse events have been reported in the Pfizer Safety database. To characterize the type and reporting rate of adverse events reported in patients receiving tofacitinib for Psoriatic Arthritis or Rheumatoid Arthritis reported in the Pfizer Safety database.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elke Binder

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2022

Actual: 16/09/2022

Study start date

Planned: 22/09/2022

Actual: 03/10/2022

Date of final study report

Planned: 06/09/2023

Actual: 13/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921421 Non-Interventional Protocol Study Version 1.0_ 30 August 2022_Redacted.pdf(3.1 MB)

A3921421 Non-Interventional Protocol Study Amendment 1_v2.0_(clean) 07 December 2022_Redacted.pdf(3.23 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:

Safety study (incl. comparative)

Main study objective:

To characterize the type and reporting rate of adverse events in patients receiving tofacitinib for Psoriatic Arthritis or Rheumatoid Arthritis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Psoriatic arthropathy

Rheumatoid arthritis

Population studied

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)

Estimated number of subjects

73525

Study design details

Outcomes

Types and reporting rates of treatment emergent adverse events reported for patients treated with Tofacitinib for the indication of Psoriatic Arthritis or Rheumatoid Arthritis. This will include: Adverse Events and Serious Adverse Events

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Data analysis plan

All analyses for this study will be descriptive. Data output per indication will be in the form of Case Level Summaries (Demographics and clinical characteristics), Drug level summaries (AEs/SAEs/discontinuations due to AEs) and Adverse Event Reporting Proportion (Reported as SOC and Preferred Term PT, most frequent AEs, AESIs) and Case Listings (SAEs/death) from reports generated from the Pfizer safety database. AESI category data will be generated using pre-defined PTs used in PBRER. Cumulative exposure rates will be generated using IQVIA Health's MIDAS database as described in Section 9.2. RRs will be calculated using the number of AE/SAEs/most frequent AEs/AESIs reported within the study timeframe (November 6th, 2012 to November 6th, 2021).

Documents

Study results

A3921421 Non-Interventional Study Report Abstract 13 November 2023_Redacted.pdf(158.26 KB)

Study, other information

A3921421 Non Interventional Study Abstract (clean)_v2.0_07Dec2022_Redacted.pdf(1.72 MB)

A3921421 Non Interventional Study Abstract 30 August 2022_Redacted.pdf (9.26 MB)

A3921421 Non-Interventional Study Report 13 November 2023_Redacted.pdf
(8.54 MB)

Data management

Data sources

Data source(s), other

Pfizer Safety Database United States, IQVIA Health database United States

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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