An Active Surveillance, Post Authorization Safety Study (PASS) of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Interest among Patients Treated with Tofacitinib for Moderately to Severely Active Rheumatoid Arthritis (RA) within the German Registry Rheumatoide Arthritis: Beobachtung der Biologika Therapie (RABBIT) (Safety of tofacitinib in RABBIT)

First published: 05/09/2019

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS31164

Study ID

49399

DARWIN EU® study

No

Study countries

☐ Gibraltar

Study description

Rationale and background: Tofacitinib is a potent, selective inhibitor of the Janus kinase (JAK) family of kinases with a high degree of selectivity relative to other kinases in the human genome. Tofacitinib was approved in the European Union (EU) in March 2017 at a dose of 5 mg administered twice daily (BID) for the treatment of adult patients with moderately to severely active RA who have responded inadequately to, or who are intolerant to, one or more disease modifying antirheumatic drugs (DMARDs). To enable assessment of adverse outcomes of special interest including rare events and endpoints with long latency periods, Pfizer will implement a post approval, active surveillance study of tofacitinib exposed patients using actively collected prospective data in the RABBIT registry. Research Question: What are the rates of adverse outcomes of special interest in RA patients treated with tofacitinib in relation to those treated with biologic DMARDs (bDMARD) and non biologic DMARDs (nbDMARD)?

Study status

Ongoing

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

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/04/2016

Study start date

Planned: 01/09/2019

Actual: 01/09/2019

Date of interim report, if expected

Planned: 14/03/2021

Date of final study report
Planned: 14/08/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921317_PROTOCOL_RABBIT PASS v1.0 21 August 2019.doc.pdf (1.56 MB)

A3921317_PROTOCOL- RABBIT PASS _V4.0_22FEB2023.pdf (377.9 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate the rates of serious infections, malignancy, CV, and other specified outcomes among patients with RA in a German register who initiate tofacitinib. Rates will also be estimated among existing cohorts of bDMARD and nbDMARD patients to provide context for rates observed on tofacitinib. No a priori hypotheses will be tested in this descriptive study

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XELJANZ

Medical condition to be studied

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

500

Study design details

Data analysis plan

The initial analyses will consist of descriptive comparisons of baseline status and crude event rates between the different cohorts. The final analysis of endpoints will provide the rates of events overall and in subgroups defined by baseline characteristics. Pending feasibility, rates of malignancy, serious infection, CV and other event rates will be compared between tofacitinib treated RA patients and the comparator cohorts using methods that adjust for sex, age, year of treatment start, treatment history, disease severity, comorbidities, and other potential confounders.

Documents

Study, other information

A3921317_PROTOCOL VERSION 3.0_14Feb2022.pdf (558.7 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

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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