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 Swedish, Population based, Anti Rheumatic Treatment in Sweden (ARTIS) register. (Safety of tofacitinib in ARTIS)

First published: 05/09/2019

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS31157

Study ID

49403

DARWIN EU® study

No

Study countries

Sweden

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 milligrams (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 safety events 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 included in the ARTIS register. Research Question: What are the rates of safety events of special interest in RA patients treated with tofacitinib and among RA patients treated with other advanced targeted therapies?

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

Shahar Shmuel shahar.shmuel@pfizer.com

Study contact

shahar.shmuel@pfizer.com

Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/05/2018

Study start date

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

A3921314 Final Non-Interventional Protocol, 20 August 2019.doc.pdf (2.12 MB)

A3921314_PROTOCOL- ARTIS PASS _V4.0_22FEB2023.pdf (581.11 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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 estimate the rates of serious infections, malignancy, CV and other safety events of interest among patients with RA in Sweden who initiate tofacitinib. Rates will also be estimated among RA patients who initiate biologic DMARDs (bDMARDs), bDMARD and targeted synthetic DMARD (tsDMARD) naïve RA patients, and the general population to provide context for tofacitinib rates.

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

344

Study design details

Data analysis plan

descriptive summaries of baseline variables and crude rates of safety event of interest included in ARTIS. An interim and final analysis of endpoints will describe the rates of events overall with supplemental linked data. Pending feasibility, comparative, adjusted analyses that control for sex, age, year of treatment start, treatment history, disease severity, comorbidities, and other potential confounders will be performed for a final report

Documents

Study, other information

A3921314_PROTOCOL VERSION 3.0_14Feb2022.pdf (864.22 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish prescribed drug register

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