A Retrospective Database Study to Evaluate Rates of Influenza and Related Diagnoses between Patients Treated with Tofacitinib and Other Systemic Therapies within Cohorts of RA, PsA, and UC Patients: A Post-Authorization Safety Study of Tofacitinib

First published: 16/02/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39242

Study ID

50329

DARWIN EU® study

No

Study countries

United States

Study description

Patients with immune-mediated diseases such as rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ulcerative colitis (UC) are known to have an increased risk of infections compared to the general population. As such, it is important to assess the safety of tofacitinib and other treatments in this patient population. The research questions addressed by this study is: what are the rates of influenza and influenza like illness, including associated morbidity and death, among persons prescribed tofacitinib or other systemic treatments among groups of patients with RA, PsA and UC? The objectives for this study are: (1) to describe demographics and clinical characteristics of RA, PsA, and UC patient cohorts overall and within each treatment group and (2) to describe the frequency, incidence rates and clinical outcomes of influenza infections and influenza-like illness and their complications in patients receiving tofacitinib and other systemic therapies within RA, PsA and UC cohorts, stratified by age (<65 and 65 and older). This is a retrospective records-based cohort study involving secondary analysis of Optum Electronic Health Record databases in the United States consisting of longitudinal health information about patients derived from participating healthcare provider organizations.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/01/2021

Actual: 26/01/2021

Study start date

Planned: 15/02/2021

Actual: 15/02/2021

Data analysis start date

Planned: 15/02/2021

Actual: 15/02/2021

Date of final study report
Planned: 31/01/2023

Actual: 11/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

FINAL A3921383 Non-Interventional Protocol Study 01 December 2020.pdf (1.86 MB)

A3921383 Non-Interventional Protocol Study Amendment 1 (CLEAN) 29 October 2021_Redacted.pdf (3.09 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the rates of influenza and influenza like illness, including associated morbidity and mortality, among persons prescribed Xeljanz or other systemic therapies among cohorts of patients with RA, PsA and UC

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective record-based study

Study drug and medical condition

Medicinal product name

XELJANZ

Medical condition to be studied

Rheumatoid arthritis

Psoriatic arthropathy

Colitis ulcerative

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC) received treatment with tofacitinib and other systemic therapies identified from the Optum database for the study period of 1 June 2014 through 31 May 2019.

Inclusion criteria:

1. Age ≥18 years at index date.
2. Evidence of at least 1 inpatient diagnosis code or 2 outpatient diagnosis codes 7-365 days apart for RA, PsA, or UC.
3. Evidence of initiation for at least 1 approved systemic treatment (tofacitinib, JAKi, TNFi, non-TNFi, csDMARD) for the corresponding identified indication.
4. At least 180 days of continuous enrollment in prior to index date.

Exclusion criteria:

1. Evidence of >1 indications of interest during the whole study period.

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

Other

Special population of interest, other

Patients with rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis

Estimated number of subjects

199697

Study design details

Outcomes

To describe demographics, comorbidities and clinical characteristics of RA, PsA, and UC patient. To describe the frequency, incidence rates and clinical outcomes of influenza infections and influenza like illness and their complications.

Data analysis plan

Baseline demographics, comorbidities and clinical characteristics will be analyzed using baseline data for RA, PsA and UC patients, then stratified by index treatment and age. The frequency and incidence rates for influenza and influenza like illness among patients treated for RA, PsA, and UC in subsets of patients defined by different index treatments will be provided, the frequency of influenza complications, drug use around influenza diagnosis, influenza-related hospitalization and mortality among these patients will also be

provided. By influenza season analysis will be performed when applicable.

Documents

Study results

A3921383 Non Interventional Study Report Abstract 10 February 2023_Redacted.pdf (287.26 KB)

Study report

A3921383 Non Interventional Study Report 10 February 2023_Redacted.pdf (8.19 MB)

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)

Administrative healthcare records (e.g., claims)

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