Risk of Safety Events Among Patients with UC and PsA Treated with Tofacitinib and Other Advanced Treatments in the United States

First published: 19/04/2023

Last updated: 14/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105306

EU PAS number

EUPAS103443

Study ID

105306

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional study aims to provide additional information about incidence rates for specific safety outcomes in ulcerative colitis and psoriatic arthritis populations in routine clinical practice in the United States.

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

Milena Gianfrancesco

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/10/2022

Actual: 28/10/2022

Study start date

Planned: 31/03/2023

Actual: 19/04/2023

Data analysis start date

Planned: 31/12/2024

Actual: 18/08/2023

Date of final study report

Planned: 30/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921431 Non-Interventional Study Protocol v1.0 (PASS)_22 February 2023_Redacted.pdf(1005.83 KB)

A3921431 Non-Interventional Study Protocol V3.0 18Nov2024.pdf(243.52 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Incidence rates of select safety outcomes

Main study objective:

This non-interventional study aims to provide additional insights into incidence rates of select safety outcomes in ulcerative colitis and Psoriatic arthritis populations using active comparator groups in routine clinical practice in the United States.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Colitis ulcerative

Psoriatic arthropathy

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

1

Study design details

Outcomes

Primary outcomes in this study include incidence rates in patients on tofacitinib and other forms of advanced treatment of the following safety events: major adverse cardiovascular events, venous thromboembolic disease (defined as deep vein thrombosis and pulmonary embolism), malignancy (excluding non-melanoma skin cancer) and serious infections.

Estimates of safety events will be stratified by the following factors:

1. Age: younger than 50 years or at least 50 years and older
2. Age: younger than 65 years or at least 65 years and older
3. Systemic glucocorticoid use at baseline
4. Previous biologic or other advanced treatment used prior to baseline
5. History of major adverse cardiovascular events or venous thromboembolic diseases

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Data analysis plan

This is a descriptive analyses.

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan.

Baseline demographic and clinical characteristics will be tabulated among the two cohorts of patients (ulcerative colitis and Psoriatic arthritis), and each exposure category within the disease cohorts. Incidence rates for select safety

events will be calculated with person-time at risk starting on the index date and ending on the date of a censoring event.
Statistical methods for propensity score matching will be detailed in the statistical analysis plan.
Hazard rates will be estimated using an inverse probability weighted Cox proportional hazards model with time since treatment start as timescale.

Documents

Study, other information

A3921431 Non Interventional PASS ABSTRACT 22Feb2023_Redacted.pdf(323.73 KB)

A3921431 Non-Interventional Study Protocol V3.0 18Nov2024.pdf(243.52 KB)

Data management

Data sources

Data source(s), other

Optum’s Clinformatics United States, Komodo Health United States

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