An Active Surveillance, Post-Authorisation Study to Characterize the Safety of Tofacitinib in Patients with Moderately to Severely Active Ulcerative Colitis in the Real-World Setting Using Data from the Swedish Quality Register for Inflammatory Bowel Disease (SWIBREG)

First published: 16/03/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40825

EU PAS number

EUPAS40131

Study ID

40825

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

This is a 6-year active surveillance, secondary data collection study of adult UC patients aged ≥18 years using data in SWIBREG linked via unique patient identifiers to existing nationwide health registers in Sweden. Due to a one-year lag associated with linking SWIBREG to other Swedish national registers (essential for the assessment of safety events associated with UC therapy), and to allow for a minimum follow-up duration of 12 months, UC patients meeting the study entry criteria through 31 March 2024 will be included in the analysis, follow-up of patients for the study will end 31 March 2025, and end of data collection will be 31 March 2026 when the full dataset with completed linkages will be available for analysis. Incidence rates and associated 95% confidence intervals (CIs) of the safety events of interest will be calculated in all four cohorts. Data capture and follow up methods are the same for the tofacitinib treatment cohort and the 3 comparator treatment cohorts within the Swedish Registers. For both primary and secondary safety events of interest, comparative analyses will be conducted as feasible.

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

Nana Koram

Study contact

nana.koram@pfizer.com

Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/06/2019

Study start date

Planned: 31/03/2021

Actual: 31/03/2021

Data analysis start date
Planned: 31/03/2026

Date of interim report, if expected
Planned: 31/08/2022

Date of final study report
Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Final_A3921344_Amended Protocol_SWIBREG PASS__11.17.2020_clean_QC complete.pdf(853.25 KB)

A3921344_PROTOCOL- SWIBREG PASS CLEAN QC COMPLETE_V5.0_09FEB2022.pdf(929.45 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:

The primary objective is to estimate the incidence rates of malignancy, excluding non-melanoma skin cancer and venous thromboembolism among adult UC patients aged ≥18 years who initiate tofacitinib in the course of routine clinical care, as well as the incidence rates in UC patients treated with other approved systemic agents.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TOFACITINIB CITRATE

Medical condition to be studied

Colitis ulcerative

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

Outcomes

Malignancy, excluding non-melanoma skin cancer, and venous thromboembolism, Non-melanoma skin cancer, serious infections, opportunistic infections, herpes zoster, major adverse cardiac events, progressive multifocal leukoencephalopathy, gastrointestinal perforations, all-cause mortality

Data analysis plan

This study will include descriptive summaries of baseline characteristics of tofacitinib and comparator cohorts. Crude incidence rates (with corresponding

95% confidence intervals) of safety events of interest will be estimated for each cohort. Pending feasibility, incidence rates of all safety events of interest will be compared between tofacitinib and comparator cohorts using propensity score matched multivariable Cox regressions adjusting for potential confounders. Additionally, incidence rates of the primary safety events of interest will be stratified by prior biologic use, patient age, tofacitinib maintenance dose, and patients with ≥1 venous thromboembolism risk factors vs. none. Pending feasibility, comparative measures between tofacitinib and comparator cohorts will be conducted, otherwise crude and age-adjusted rates will be presented along with 95% confidence intervals for all four cohorts.

Data management

Data sources

Data sources (types)

Disease registry

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