A Long-Term, Observational Study within the Corrona Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting

First published: 28/06/2019

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS30314

Study ID

34556

DARWIN EU® study

No

Study countries

United States

Study description

The goal of the study is to characterize the safety of tofacitinib (all approved formulations) in ulcerative colitis (UC) patients in the post-approval setting. The primary outcome of interest is malignancy, excluding non-melanoma skin (NMSC).

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: 07/03/2019

Study start date
Planned: 30/06/2019

Actual: 30/06/2019

Date of interim report, if expected
Planned: 30/06/2024

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Final_Protocol_A3921329_Tofacitinib UC Corrona PASS_6.5.2019_REDACTED.pdf

(928.31 KB)

FINAL_Protocol_A3921329_Tofacitinib UC Corrona PASS_1.24.2020_REDACTED.pdf (690.08 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

A3921329

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 assess the incidence of malignancy, excluding non-melanoma skin cancer (NMSC), in adult UC patients exposed to tofacitinib (all approved formulations) in the course of routine clinical care compared to other medications approved to treat UC.

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

6858

Study design details

Outcomes

Malignancy, excluding non-melanoma skin cancer (NMSC) in adult UC patients exposed to tofacitinib (all approved formulations) in the course of routine clinical care compared to other medications approved to treat UC, NMSC, opportunistic infections, major adverse cardiac events, thromboembolic events (deep venous thrombosis and pulmonary embolism), hepatic events (serious or requiring liver biopsy), serious infections, herpes zoster, progressive multifocal leukoencephalopathy, gastrointestinal perforations, surgery for UC and all-cause mortality

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Data analysis plan

Counts and proportions, unadjusted cumulative incidence proportions, unadjusted incidence rates (number of events/person-years) and associated two-sided 95% confidence intervals will be calculated as appropriate and compared between groups for all safety outcomes. Pending data availability, subgroup analyses (disease severity, tofacitinib dose, prior treatment group and/or comorbidity status) may be performed. The primary summary of reporting rates of events will be based on survival analysis of time to first event based on an index date defined for each population with appropriate censoring rules applied for those who do not experience an event by end of follow-up period. Rates will be expressed as events/100 person-years of follow-up. A Cox regression model will be estimated to analyze time to first event for each safety outcome and compare rates of events between the tofacitinib study population and two defined comparator groups (biologics and immunosuppressant groups).

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

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