12- and 18-Month Outcomes and Long-Term Survival of Tofacitinib in Ulcerative Colitis

First published: 23/02/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44985

Study ID

50427

DARWIN EU® study

No

Study countries

☐ United States

Study description

Outcomes and Long-Term Survival of Tofacitinib in patients with Ulcerative Colitis

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Networks

Mass General Brigham (MGB)

Contact details

Study institution contact

Puza Sharma Puza.Sharma@pfizer.com

Study contact

Puza.Sharma@pfizer.com

Primary lead investigator

Edith Owens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2021

Actual: 06/12/2021

Study start date

Planned: 01/03/2022

Actual: 24/02/2022

Date of final study report

Planned: 30/03/2023

Actual: 20/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921416 Non Interventional Study Protocol Final 08Feb2022_Redacted.pdf (1.88 MB)

A3921416 Non Interventional Study Protocol Amendment 2_clean 06Jun2022_Redacted.pdf(2.52 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 type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To perform a retrospective cohort study to assess long-term clinical outcomes at 52 and 78 weeks of tofacitinib therapy for Ulcerative Colitis.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

Patients with ulcerative colitis aged 18 years or older received tofacitinib therapy after 1 May 2018 identified in the Mass general Brigham (MGB) health system.

Inclusion criteria:

1. Age 18 years or older.
2. Initiation of tofacitinib therapy for ulcerative colitis on or after May 1, 2018.
3. Patients within the MGB health system.

Exclusion criteria:

1. History of prior colectomy.
2. Primary indication of tofacitinib therapy is not ulcerative colitis.
3. Diagnosis of Crohn's disease or intermediate colitis.
4. Combination biologic therapy (eg., tofacitinib and vedolizumab simultaneously).

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 ulcerative colitis

Estimated number of subjects

100

Study design details

Outcomes

Assess proportions of clinical remission (Simple Clinical Colitis Activity Index (SCCAI) or Mayo less than or equal to 2 or Physician global assessment (PGA)) and corticosteroid-free clinical remission (with no use of corticosteroids within 30 days preceding assessment) at week 52 and 78 after tofacitinib induction in a real-world cohort of patients with Ulcerative Colitis. Univariable and multivariable logistic regression to identify baseline predictors of corticosteroid-free clinical remission (with no use of corticosteroids within 30 days preceding assessment) at weeks 52 and 78.

Data analysis plan

Descriptive statistics will be presented to describe patient characteristics. Categorical covariates will be described by frequency distribution while continuous covariates expressed in terms of their mean and standard deviation or median and interquartile range (IQR) as appropriate. Univariate and multivariable logistic regression models will be used to identify predictors (among all independent variables) of corticosteroid-free remission at Week 52 and week 78(2 separate models). Variables from the univariable analysis that are statistically significant at $p<0.10$ will be included in the final multivariable model. Adjusted odds ratios with 95% confidence intervals will be calculated using logistic regression models and reported in the final models. Patients who die prior to assessment of endpoints will be excluded from the logistic regression analysis.

Documents

Study results

A3921416 NI Study Report 19 November 2022_Redacted.pdf(3.06 MB)

A3921416 NI Study Report Abstract 19 November 2022_Redacted.pdf(516.22 KB)

Study, other information

A3921416 Non Interventional Study Abstract_Amendment 2_06Jun2022_Redacted.pdf(1.86 MB)

A3921416 Non Interventional Study Abstract_Final 08Feb2022_Redacted.pdf (1.7 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)

Electronic healthcare records (EHR)

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