Real world evidence of the usage of tofacitinib in Ulcerative Colitis patients in Lebanon

First published: 24/11/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38515

Study ID

48631

DARWIN EU® study

No

Study countries

Lebanon

Study description

A retrospective cohort study that describes the effectiveness of tofacitinib for the treatment of patients with ulcerative colitis in Lebanon.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

American University of Beirut

Contact details

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Study contact

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Primary lead investigator

Owens Edie

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/11/2021

Actual: 08/11/2021

Study start date
Planned: 30/11/2021

Actual: 30/11/2021

Date of final study report
Planned: 30/03/2023

Actual: 23/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921393 Non_interventional Study Protocol 19 May 2021.pdf (1.84 MB)

A3921393 Non_interventional Study Protocol amendment 1 V2 29 Apr 2022_clean_Redacted.pdf (340.93 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

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:

The objective of this study is to describe the effectiveness of tofacitinib in the treatment of ulcerative colitis in a Lebanese cohort

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational retrospective study

Study drug and medical condition

Medicinal product name

XELJANZ

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

TOFACITINIB CITRATE

Medical condition to be studied

Colitis ulcerative

Inflammatory bowel disease

Crohn's disease

Population studied

Short description of the study population

The study population involved patients aged 18 years or older diagnosed with ulcerative colitis initiated treatment with tofacitinib identified from the database of American University of Beirut Medical Center (AUBMC).

Inclusion Criteria:

1. Male or female patients 18 years or older by the time of starting tofacitinib treatment
2. Confirmed diagnosis of ulcerative colitis.
3. Patients who have received treatment with tofacitinib for ulcerative Colitis with minimal follow-up period of 12 weeks.

Exclusion Criteria:

1. Current or previous (within the last 2 years) indeterminate or not classified colitis.
2. Changing of IBD type (ie, from UC to Crohn’s disease (CD), etc.) within the last 2 years.
3. Any combinations of tofacitinib with other advanced therapies.
4. Any previous use and discontinuation of tofacitinib.

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

62

Study design details

Outcomes

Proportion of patients achieving clinical remission by 8 weeks, 26 weeks, and 52 weeks. Proportion of patients achieving endoscopic remission and response in ulcerative colitis as determined by the endoscopic Mayo score at 24 weeks, Proportion of patients that are still on tofacitinib treatment at 1 year. Proportion of patients requiring IBD surgery after 1 year of follow up. Changes in Calprotectin, CRP, Hemoglobin and LDL at 12 weeks compared with baseline following treatment with tofacitinib

Data analysis plan

All collected data will be analyzed. Analysis will be done by the Statistical Program for the Social Sciences (SPSS). All covariates will be summarized to get information about frequency distribution and mean, median or standard deviation. Numbers and percentages of patients who are in complete remission will be presented for weeks 8, 26, and 52 when performing descriptive analysis of categorical data. Means, medians, standard deviations will be provided for continuous variables when performing descriptive analysis of continuous data. The bivariate analysis will be conducted to determine if there is any association between the outcome and the exposure (the covariates). Unadjusted comparisons of baseline characteristics for 8, 26, and 52 weeks after complete remission against outcome measures will be provided. Appropriate tests will be used based on the distribution of the measure:

Documents

Study results

A3921393 Non-Interventional Study Report 11 January 2023_Redacted.pdf (3.75 MB)

Study report

A3921393 Non-Interventional Study Report Abstract 11 January 2023_Redacted.pdf (302.77 KB)

Study, other information

A3921393_Study Abstract V1.0 14 Jun 2021.pdf (42.77 KB)

A3921393_Study Abstract V2.0 29 Apr 2022.pdf (47.59 KB)

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