Comparative Effectiveness of Tofacitinib Versus Ustekinumab and Vedolizumab among Ulcerative Colitis Patients With Prior Anti- Tumor Necrosis Factor (TNF) Failure

First published: 23/02/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS45035

Study ID

46622

DARWIN EU® study

No

Study countries

United States

Study description

To perform a retrospective matched cohort study to compare clinical outcomes of these agents among anti-TNF exposed patients with Ulcerative Colitis in our health system.

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: 29/10/2021

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: 13/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921415 Non Interventional Study Protocol Final 08Feb2022_Redacted.pdf (1.87 MB)

A3921415 Non Interventional Study Protocol Amendment 1 (clean) 08Apr2022 (1)_Redacted.pdf (1.98 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)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To asses how tofacitinib, ustekinumab and vedolizumab compare in real world safety and effectiveness of anti-TNF-experienced ulcerative colitis patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medicinal product name

XELJANZ

ENTYVIO

STELARA

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

Patients with ulcerative colitis (UC) aged 18 years or older initiated treatment with tofacitinib, ustekinumab, or vedolizumab therapy on or after 01 May 2018 through 01 February 2022 identified from the Mass General Brigham (MGB) health system.

Inclusion Criteria:

1. Age of 18 years or older.
2. Initiation of tofacitinib, ustekinumab, or vedolizumab therapy for UC on or after 01 May 2018 through 01 April 2022.
3. Prior anti-TNF exposure.
4. Patient within the MGB health system.

Exclusion Criteria:

1. History of prior colectomy.
2. Primary indication of tofacitinib, ustekinumab, or vedolizumab therapy is not UC.
3. Diagnosis of Crohn’s disease or indeterminate colitis.
4. Dual therapy with tofacitinib and a biologic (eg, tofacitinib and vedolizumab or ustekinumab simultaneously) or vedolizumab/ustekinumab and a second biologic.

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

360

Study design details

Outcomes

Compare proportions of corticosteroid-free clinical remission 8-12 weeks and 52 weeks after tofacitinib, ustekinumab or vedolizumab initiation by using either SCCAI or Mayo score by greater than or equal 2 or physician global assessment. Compare drug survival (time to treatment discontinuation or colectomy) of tofacitinib versus ustekinumab and vedolizumab. Compare proportions of endoscopic response, endoscopic remission. Assess proportions of biochemical response and remission. Compare proportions of colectomy, IBD-related hospitalization, and corticosteroid use, proportions of patient-reported improvement in extra intestinal manifestations, proportions of potential complications and treatment discontinuations.

Data analysis plan

After patient cohorts are identified in the MGB RPDR using the pre-specified inclusion and exclusion criteria, vedolizumab patients will be frequency matched 2:1 to tofacitinib patients by age (±3 years) and sex. The matched sample will be used for all subsequent analyses for this comparison. All eligible ustekinumab patients will be used in the tofacitinib vs ustekinumab comparison. De identified data will be imported into StataSE 17 for statistical analysis.

Documents

Study results

A3921415 Non Interventional Study Report Abstract 22 December 2022_Redacted.pdf (1.54 MB)

Study report

A3921415 Non Interventional Study Report 22 December 2022_Redacted.pdf (4.08 MB)

Study, other information

A3921415 Non Interventional Study Abstract_Amendment 1 08Apr2022_Redacted.pdf (1.7 MB)

A3921415 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 source(s), other

Mass General Brigham (MGB) Research Patient Data Registry (RPDR)

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