A network meta-analysis of real-world studies comparing tofacitinib with other advanced therapies in the treatment of moderate-to-severe ulcerative colitis

First published: 15/01/2024

Last updated: 19/03/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/199008

EU PAS number

EUPAS108141

Study ID

199008

DARWIN EU® study

No

Study countries

United States

Study description

The study is designed as a NMA (network meta-analysis) with the primary objective to compare the effectiveness of tofacitinib with other advanced therapies in real-world studies for the treatment of patients with moderate-to-severe UC (ulcerative colitis).

The secondary objective of the study is to compare the safety outcomes as IR assessed through a meta-analysis of tofacitinib and other advanced therapies in real-world studies of patients with moderate-to-severe UC.

These analyses will be performed on data collected from studies published in literature in the form of a systematic literature review (SLR) and no patient enrollment will be done.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

ConnectHEOR Limited

Contact details

Study institution contact

Milena Gianfrancesco

Study contact

Milena.Gianfrancesco@pfizer.com

Primary lead investigator

Milena Gianfrancesco

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/11/2023

Study start date

Planned: 17/01/2024

Actual: 16/01/2024

Data analysis start date

Planned: 18/01/2024

Date of final study report

Planned: 15/03/2025

Actual: 11/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921447_Non-Interventional Study Protocol V1.0_2Jan2024_FINAL -R.pdf (306.43 KB)

A3921447_Protocol_V2.0_09Dec2024_R.pdf(370.17 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

Study type:

Not applicable

Scope of the study:

Feasibility analysis

Main study objective:

To compare the effectiveness and safety of tofacitinib with other advanced therapies in real-world studies for the treatment of patients with moderate-to-severe UC.

Study drug and medical condition

Name of medicine

XELJANZ

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

TOFACITINIB CITRATE

Anatomical Therapeutic Chemical (ATC) code

(L04AF01) tofacitinib

tofacitinib

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

A total of 246 studies will be included in this network meta analysis; the actual number of patients in each study will be determined after data analysis.

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)

Study design details

Outcomes

1.To estimate the difference in the likelihood of achieving a clinically meaningful response, in terms of effectiveness outcomes, between patients treated with tofacitinib compared to other advanced therapies.

2. To estimate the relative risk of serious adverse events (AEs) between patients treated with tofacitinib versus other advanced therapies

Are there secondary outcomes?

3. To estimate the incidence rate (IR) of various AEs, and of mortality, on each therapy.

Data analysis plan

In the following, two approaches have been planned to performing the NMA, (i) contrast-based models which perform the synthesis of data on relative treatment effects between study arms, and (ii) arm-based models which perform the synthesis of data on absolute effects across study arms. Both approaches can be applied to estimate an overall pooled relative effect.

Documents

Study report

A3921447 Study Report 27Jan2025.pdf(1.45 MB)

A3921447 Study Report Abstract.pdf(73.76 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Electronic biomedical literature databases

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