REal Life Safety and effectiveness of tofAcitinib in comparison to TNF InhibitOrs using the French National Healthcare Database (RELATION)

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Study Ongoing

Administrative details

EU PAS number

EUPAS41054

Study ID

46290

DARWIN EU® study

No

Study countries

France

Study description

The objectives of this study are mainly to assess tofacitinib safety compared to TNF inhibitors or vedolizumab through French national healthcare database. This study will be performed separately for the rheumatology (RA, and PsA), and for the gastroenterology patients (UC).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Networks

HEVA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elke Binder

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2020

Actual: 12/10/2020

Study start date

Planned: 31/01/2022

Actual: 03/03/2022

Date of final study report

Planned: 28/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921399 Non-Interventional Protocol 30 April 2021.pdf (4.78 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Safety comparison between tofacitinib and TNF inhibitors/ vedolizumab among RA and UC patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XELJANZ

Medical condition to be studied

Psoriatic arthropathy

Rheumatoid arthritis

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

1

Study design details

Outcomes

Incidence of malignancies, excluding non-melanoma skin cancer and acute cardiovascular events with tofacitinib vs TNFi or vedolizumab (VDZ), separately for UC, RA, and PsA patients. Co-primary endpoint according to age (below and above 65yo) Incidence of serious infections and thromboembolic events with tofacitinib vs TNFi or VDZ, according to age. Treatment duration and persistence of tofacitinib, TNFi or VDZ. Effectiveness of tofacitinib vs TNFi or VDZ.

Data analysis plan

Analyses will be performed separately per type of IMID (RA, PsA, UC). For both primary and secondary safety objectives, a Cox model will be used. In case of sufficient power, a marginal structural Cox proportional hazard regression models (MSM) will also be implemented. Descriptive statistics will be used to describe demographic characteristics of patients treated with tofa, TNFi and vedolizumab. Competing Risk Model – Fine & Gray will be used to compare the effectiveness of tofacitinib vs TNFi.

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.

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