Real-world comparative effectiveness of tofacitinib, tumour necrosis factor inhibitors, and interleukin 17 inhibitors among patients with axial spondylarthritis and psoriatic arthritis

First published: 15/11/2024

Last updated: 29/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000226

Study ID

1000000226

DARWIN EU® study

No

Study countries

United States

Study description

This is a non-interventional, population-based retrospective cohort study of adults (ages ≥18 years of age) with Axial spondylarthritis (AxSpA), and Psoriatic arthritis (PsA) identified through a United States (US) administrative claims database.

This study aims to provide data on the comparative real-world clinical effectiveness of advanced therapies (tofacitinib, TNFi, and IL-17i) as well as their associated costs and resource utilization.

The results are intended to provide useful information to healthcare professionals and patients in clinical decision making for patients with these conditions.

De-identified individual who initiated one of the study treatments will be selected from a database between December 14, 2021, and most recent data available for the AxSpA sample and December 14, 2017, and most recent data available for the PsA sample.

The index date will be defined as the date of initiation (first time use) of one of the selected treatments (ie, tofacitinib, TNFi or IL-17i) within the specified identification period for each sample. Patients will be required to have at least 12 months of continuous enrollment (medical and pharmacy benefits) prior to the index date and at least 6 months after the index date.

Analysis will be replicated for a subset of patients with at least 12 months of continuous enrollment after the index date.

The baseline period will be defined as the 12 months before index date.

Patient’s demographic and clinical characteristics will be characterized at index date or during the baseline period, depending on the study variable. Treatment effectiveness and healthcare resource utilization and costs will be assessed over the 6 and 12 months following the index date.

Persistence on the index treatment will be assessed over the 12 months following the index date.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Komodo Health

Contact details

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Study contact

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Primary lead investigator

Genevieve Gauthier

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/04/2024

Actual: 05/04/2024

Study start date
Planned: 05/02/2025

Actual: 18/02/2025

Date of final study report
Planned: 15/05/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921446_Protocol_V1_23AUG2024_ REDACTED.pdf (1.1 MB)

A3921446 Protocol_V3.0_10JULY2025_FINAL_Redacted.pdf (916.27 KB)

A3921446 Protocol V 2.0 dated 03 JAN 2025_FINAL_Redacted.pdf (886.66 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Main study objective:

Primary objectives:

1. To compare the proportion of AxSpA patients fulfilling effectiveness criteria within 6 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 6 months of continuous enrollment after index date.

2. To compare the proportion of b/tsDMARD-naïve PsA patients fulfilling effectiveness criteria within 6 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 6 months of continuous

enrollment after index date.

Secondary objectives:
1. To compare the proportion of AxSpA patients fulfilling effectiveness criteria within 12 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
2. To compare the proportion of b/tsDMARD-naïve PsA patients fulfilling effectiveness criteria within 12 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
3. Evaluate drug persistence (median time to therapy discontinuation) among AxSpA patients within 12 months of treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
4. Evaluate drug persistence (median time to therapy discontinuation) among b/tsDMARD-naive PsA patients within 12 months of treatment with tofacitinib vs TNFi vs IL-17i among the sample of patients with at least 12 months of continuous enrollment after index date.
5. Evaluate health care resource utilization and cost data for AxSpA patients within 6 and 12 months of treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 6 or 12 months of continuous enrollment after index date, respectively.

Study drug and medical condition

Medicinal product name

XELJANZ

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

TOFACITINIB

Medical condition to be studied

Axial spondyloarthritis

Additional medical condition(s)

Psoriatic Arthritis

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

Komodo’s Healthcare Map database

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

Unknown