Real-world evaluation of effectiveness, persistence and usage patterns of tofacitinib in treatment of psoriatic arthritis in Australia.

First published: 17/05/2021

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39635

Study ID

48796

DARWIN EU® study

No

Study countries

Australia

Study description

To understand the treatment patterns, clinical effectiveness, patient reported outcomes and treatment persistence among Australian adult patients with psoriatic arthritis

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

OPAL Rheumatology Limited

Contact details

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Study contact

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Primary lead investigator

Edie Owens

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2020

Actual: 29/06/2020

Study start date
Planned: 31/05/2021

Actual: 15/05/2021

Date of final study report
Planned: 01/11/2022

Actual: 28/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921398 Final Non-Interventional Protocol Study Abstract.pdf (1.24 MB)

A3921398 Non-Interventional Study Protocol 04 March 2021.pdf (1.87 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To understand the patterns of treatment (lines of therapy, and use as combination or monotherapy), clinical effectiveness, PROs and treatment persistence among Australian adult patients with PsA treated with tofacitinib. Data will also be collected for patients treated with bDMARDs to provide descriptive information about clinical management of PsA in real world Australian clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective structured data analysis

Study drug and medical condition

Medicinal product name

XELJANZ

Medical condition to be studied

Psoriatic arthropathy

Population studied

Short description of the study population

Adults patients aged 18 years or older diagnosed with psoriatic arthritis receiving treatment with tofacitinib or a biologic disease-modifying antirheumatic drug (bDMARD) identified from the OPAL database in Australia.
Inclusion criteria:
• Diagnosed with PsA;
• Aged 18 years but under 95 years of age on the index date (date of commencement of interleukin 17 inhibitor (IL17i), tumor necrosis factor inhibitor (TNFi), or tofacitinib);
• Received at least 1 prescription for IL17i, TNFi, or tofacitinib; and
• Have at least 1 year of follow-up since prescription of IL17i, TNFi, or tofacitinib.

Exclusion criteria:
• Diagnosis with any autoimmune rheumatic disease except for PsA (eg, rheumatoid arthritis, ankylosing spondylitis).
• Patients who have no visit data recorded within the sample window.
• Patients who have missing start dates for IL17i, TNFi, or tofacitinib during the sample selection window.

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

Psoriatic arthritis patients

Estimated number of subjects

1.540

Study design details

Outcomes

1. To describe tofacitinib, IL17i, and TNFi treatment patterns among Australian adult patients with PsA, including: • Line of use (eg, first-line, second-line), • Mean dose, • Proportion of patients receiving monotherapy, • Proportion of patients using in combination with NSAIDs, corticosteroids and cDMARDs, • Reasons for discontinuation. Describe treatment persistence to IL17i, TNFi and tofacitinib in patients with PsA. Describe the clinical effectiveness of tofacitinib, IL17i, and TNFi, as defined by disease severity markers (DAS28-ESR, CDAI, SDAI, DAPSA and the percentage of patients reaching targeted treatment goals (remission or low disease activity) To describe patient reported outcomes (HAQ-DI, FACIT-Fatigue, HCRU)

Data analysis plan

All continuous variables will be summarised using n (non missing sample size), mean, standard deviation, median, minimum and maximum. The frequency and percentages (based on the non missing sample size) or observed levels will be reported for all categorical measures. Descriptive summaries will be produced for each data cut, providing there is sufficient data available, and again at the final analysis. All summaries are descriptive and there are no comparative analyses being undertaken, therefore, no adjustments for multiple data cuts and multiple endpoints are required. Patients who discontinue their index treatment (tofacitinib, TNFi or IL17i) will continue to be followed for a period of

1 year.

Documents

Study report

A3921398 Non Interventional Study Report 19 July 2022_Redacted.pdf (6.43 MB)

A3921398 Non Interventional Study Report Abstract 19 July 2022_Redacted.pdf (1.93 MB)

Study, other information

A3921398 Non Interventional Study Report Abstract 19 July 2022_Redacted.pdf (1.93 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 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