A multicenter evaluation of the treatment persistence of advanced therapies (Biological disease-modifying agents and Targeted synthetic Disease Modifying Anti-Rheumatic Drugs) in the treatment of rheumatoid arthritis (RA): A Real World Evidence (RWE) study from India

First published: 27/10/2023

Last updated: 12/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS103727

Study ID

107874

DARWIN EU® study

No

Study countries

India

Study description

This multicenter prospective study of patient charts evaluates treatment persistence, time until drug discontinuation (drug survival), effectiveness and safety of advanced therapies in Rheumatoid arthritis patients.
Patients will be enrolled in this study if they were diagnosed with Rheumatoid arthritis and are eligible for treatment with biological or targeted synthetic Disease Modifying Anti-Rheumatic Drugs as per the routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Centre for Rheumatic Diseases and Regenerative Clinical Medicine

Mumbai Arthritis Clinic and Research Center

Institute of Post-Graduate Medical Education and Research

Kalinga Institute of Medical Sciences (KIMS)

Optima Arthritis and Rheumatology Clinic

Stanley Medical College

Shanti Wellness Care

Sri Deepti Rheumatology Center

A B Rheumatology Centre

Center for Rheumatic Diseases

Networks

Insignia

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Catherine Bahus

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/12/2022

Study start date
Planned: 19/09/2024

Actual: 25/09/2024

Data analysis start date
Planned: 01/11/2025

Date of final study report
Planned: 01/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921433 Non-Interventional Study Protocol_Amendment 1_(clean)_Version 2.0_26JAN2024)_Redacted.pdf (4.75 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

A3921433

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a multicenter prospective study conducted in India to evaluate treatment persistence and drug survival on advanced therapies in rheumatoid arthritis. All assessments described in this protocol are performed as part of normal clinical practice for the patient population.

Main study objective:

Treatment persistence and drug survival in patients on the advanced therapies for rheumatoid arthritis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XELJANZ

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

TOFACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AF01) tofacitinib

tofacitinib

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Adult patients aged 18 years and over, diagnosed with rheumatoid arthritis eligible for to start treatment with advanced therapies (biological and targeted synthetic disease modifying anti-rheumatic drugs).
Patients who have started treatment with disease modifying anti-rheumatic drugs for longer than 3 months cannot be included in this study.

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

225

Study design details

Setting

The patients would be enrolled based on the inclusion and exclusion criteria. The treatment regimen will be as per treating physician (investigators) decision. Routine clinical and diagnostic evaluations will be as per standard practice guidelines, irrespective of whether the patient is participating in the study or not.

Comparators

NA

Outcomes

The percentage of patients in each class, achieving 1 year survival will be calculated. 100% of the study population considered as all patients who entered the study.
Effectiveness parameters, as the change in Disease activity score 28, Health Assessment Questionnaire disability index and psoriatic arthritis disease activity scores from baseline to the end of the study.
Number of adverse events while on treatment during the study inclusion.
Disease factors or other determinants for treatment switch and time to first and subsequent switch to advanced therapies.

Data analysis plan

In the statistical analysis plan the clinical profile of the patients will be summarized by mean ± Standard Deviation and frequency (%) respectively. Demographic parameters will be reported by suitable measure of average like mean or median if continuous otherwise frequency and percentage.
Median drug survival/ drug persistency will be compared across demographic parameters and external validity will be assessed by log-rank test.
Mean ± Standard of the score efficacy parameters will also be reported and compared across demographic parameters, external validity will be tested by

independent t-test and ANOVA or Mann-Whitney and Kruskal Wallis test. Adverse event and severity of advance event will also be compared if many across demographic parameters by percentage with 95% confidence interval.

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)

Other

Data sources (types), other

Routine primary care patient files

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

Not applicable