Characterization and outcomes follow up of patients with rheumatoid arthritis initiating tofacitinib: A retrospective, observational PASS using the British Society of Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA) A3921448

First published: 03/09/2024

Last updated: 30/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000102

Study ID

1000000102

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Voluntary, exploratory PASS study to understand baseline characteristics, continuation and efficacy outcomes for adult patients with Rheumatoid Arthritis initiating tofacitinib in the UK. This secondary data study uses data from the existing BSRBR-RA (an ongoing, prospective, observational cohort study started in 2001 with the primary aim of
studying the safety of new therapies for RA during routine post-marketed clinical use) supplied to Pfizer as part of the ongoing commitment PASS study A3921312.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Barkaway

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/10/2022

Actual: 03/10/2022

Study start date

Planned: 03/10/2022

Actual: 03/10/2022

Data analysis start date

Planned: 03/10/2022

Actual: 03/10/2022

Date of final study report

Planned: 30/09/2024

Actual: 25/09/2024

Sources of funding

- No external funding

More details on funding

Funded by Pfizer

Study protocol

A3921448 Non-Interventional Study Protocol V.1_Redacted.pdf (8.99 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

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Voluntary, exploratory PASS study to understand baseline characteristics, continuation and efficacy outcomes for adult patients with Rheumatoid Arthritis initiating tofacitinib in the UK, using the existing BSRBR-RA dataset supplied to Pfizer as part of the ongoing commitment PASS A3921312.

Main study objective:

1. To assess the feasibility, completeness and quality of the datacut from the BSRBR-RA register to address the research question and subsequent objectives
2. To describe baseline characteristics for patients initiating tofacitinib in the UK and compare to a TNFi cohort
3. To assess and quantify the proportion of patients who exhibit specific co-morbidities at baseline initiating tofacitinib and compare to a TNFi cohort
4. To describe the change in disease activity and pain scores from baseline to 36 months post tofacitinib initiation and compare to a TNFi cohort
5. Assess continuation of tofacitinib from baseline across 36 months and stratify by bio-experienced and bio-naïve populations

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

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

TOFACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AA29) tofacitinib

tofacitinib

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

The study population will comprise all patients with RA enrolled within BSRBR-RA who receive tofacitinib following EU approval and marketing, with a data cut off of November 2021. For some objectives, one comparator cohort of patients within BSRBR with active RA at cohort entry will be used. This comparator cohort consists of RA patients initiating TNFi.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

2356

Documents

Study report

A3921448 CSR_Redacted.pdf (4.6 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.

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