An Observational Study of Xeljanz® (tofacitinib citrate) and Biologic Rheumatoid Arthritis Treatments to Characterize their General Treatment Patterns, Effectiveness and Safety in a Real-World Taiwanese Population

First published: 11/05/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13431

Study ID

48622

DARWIN EU® study

No

Study countries

Taiwan

Study description

Update - administrative updates were needed to the final study report and are addressed in the summary of changed document I have attached. The main objective of this multicenter, prospective, observational comparative effectiveness study in Taiwan is to understand general treatment patterns, effectiveness, and safety of tofacitinib compared to TNFi in a non-restricted population of RA patients in the real-world setting.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Taipei Veterans General Hospital Taipei, Tri-Service General Hospital Taipei, Taichung Veterans General Hospital Taichung City, Kaohsiung Medical University Chung-Ho Memorial Hospital Kaohsiung City, Kaohsiung Veterans General Hospital Kaohsiung City, National Taiwan University Hospital Taipei City, China Medical University Hospital Taichung City

Contact details

Study institution contact

Edward Kuo Edward.Kuo@pfizer.com

Study contact

Edward.Kuo@pfizer.com

Primary lead investigator

Edith Owens

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/12/2015

Actual: 25/12/2015

Study start date
Planned: 15/04/2016

Actual: 12/08/2016

Date of final study report
Planned: 30/04/2022

Actual: 01/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921275_PROTOCOL_V1.0_01FEB2016 (for EU PAS register).pdf (638.26 KB)

A3921275 Non-Interventional PROTOCOL Amendment 1 (clean version 2) 16 March 2022_Redacted.pdf (1.92 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of this multicenter, prospective, observational comparative effectiveness study in Taiwan is to understand general treatment patterns, effectiveness, and safety of tofacitinib compared to TNFi in a non-restricted population of RA patients in the real-world setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational, multicenter, comparative effectiveness study

Study drug and medical condition

Medicinal product name

ENBREL

HUMIRA

SIMPONI

XELJANZ

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

The study involved participants aged 20 years or older who were newly prescribed tofacitinib or a tumor necrosis factor inhibitors (TNFi) for the treatment of rheumatoid arthritis (RA) in Taiwan.

Inclusion criteria:

• Adults over 20 years of age

• The patient had a clinical diagnosis of RA.

• The patient is newly prescribed tofacitinib or a TNFi (ie, Enbrel®, Humira® or Simponi®) for RA at the time of enrollment. Patients switching from one TNFi to another or from one TNFi to tofacitinib will be included as long as they are incident users of a given TNFi or of tofacitinib.

• The patient must have evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study.

• The patient is able to read, write and reply the study questionnaires.

Exclusion criteria:

• The patient is enrolled in any other clinical trial of an investigational product.

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

Patients with rheumatoid arthritis

Estimated number of subjects

500

Study design details

Outcomes

Describe the baseline characteristics of RA patients prescribed tofacitinib or TNFi Enbrel® (etanercept), Humira® (adalimumab), or Simponi® (golimumab) and evaluate whether baseline characteristics of patients treated with tofacitinib are comparable to patients prescribed TNFi within line of therapy. Describe measures of short-term and long-term effectiveness for tofacitinib and TNFi Describe safety outcomes in patients receiving tofacitinib and TNFi. The safety outcomes of interest Targeted Adverse Events (TAE) include cardiovascular events, hepatitis B and C reactivation, tuberculosis (TB), serious infections, herpes zoster, malignancy, and liver enzyme abnormalities.

Data analysis plan

Categorical variables will be summarized as proportions with 95% confidence intervals. P-values will be used to compare baseline characteristics of tofacitinib with TNFi. The effectiveness of tofacitinib will be descriptively compared to TNFi by using mixed logistic regression models with dichotomous outcome variables for HAQ-DI, CDAI and DAS-ESR. Propensity scores (PS) may be used to adjust for confounding by indication. The mean and standard deviation of WPAI-RA scores will be summarized at a given time point for each patient.

Documents

Study results

A3921275 Non Interventional Study Report Abstract 25 March 2022.pdf (109.32 KB)

Study report

A3921275 Non Interventional Study Report 25 March 2022_Redacted.pdf (2.36 MB)

A3921275 Non Interventional Study Report Summary of Changes 19Jul2022.pdf (1.24 MB)

Study, other information

A3921275 Non Interventional Study Protocol Abstract 16 March 2022.pdf (1.78 MB)

A3921275 Non Interventional Study Report Summary of Changes 19Jul2022.pdf (1.24 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)

Other

Data sources (types), other

Prospective patient-based data collection

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