Non-Interventional Study to Review the Changes of Depression after First-Year of Tofacitinib Treatment in Rheumatoid Arthritis (XELJANZ®)

First published: 01/04/2021

Last updated: 05/02/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48626

EU PAS number

EUPAS40263

Study ID

48626

DARWIN EU® study

No

Study countries

Czechia

Study description

This study is to describe and evaluate the changes of depression level within 12 months from the start of Tofacitinib therapy in patients with Rheumatoid arthritis

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

MEDICAL PLUS, s.r.o. Uherské Hradiště, Revmatologická ambulance Ostrava, Thomayerova nemocnice Prague, Revmatologický ústav Prague, RHEUMA s.r.o. Břeclav, BORMED, spol. s r.o. Ostrava-Třebovice, Revmatologie s.r.o.

Brno, Value Outcomes s.r.o

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elke Binder

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2019

Actual: 19/09/2019

Study start date

Planned: 01/06/2020

Actual: 23/07/2020

Data analysis start date

Planned: 29/02/2024

Actual: 07/02/2024

Date of final study report
Planned: 07/01/2025

Actual: 09/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921330 Final Protocol 02 April 2019_Public.pdf(7.96 MB)

A3921330 Non Interventional Study Protocol_Amendment 1 V2_clean_18Jun2021_Public.pdf(2.53 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To describe and evaluate the changes of depression level within 12 months from the start of Tofacitinib therapy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Single arm, prospective

Study drug and medical condition

Name of medicine

XELJANZ

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

TOFACITINIB

Medical condition to be studied

Rheumatoid arthritis

Depression

Insomnia

Anxiety

Arthralgia

Population studied

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

73

Study design details

Outcomes

- To find out if treatment by Tofacitinib reduces the depression by at least 10% during 12 months.
- To describe and evaluate the level and changes of pain, anxiety and insomnia in patients with RA.
- To describe the safety and effectiveness of Tofacitinib for the treatment of rheumatoid arthritis.

Data analysis plan

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a Statistical Analysis Plan (SAP). Unless

specified otherwise, continuous variables will be summarized using descriptive statistics (n, mean, SD, median, min, max) and discrete variables will be summarized using counts and percentages. To access drop-out, study flow-chart (patient disposition) between visits will be preset.

Documents

Study report

A3921330_NI STUDY REPORT_03Dec2024_Redacted.pdf(3.77 MB)

A3921330_NI STUDY REPORT ABSTRACT_03Dec2024_Redacted.pdf(237.71 KB)

Study, other information

A3921330_Abstract_18 June 2021.pdf(1.27 MB)

Data management

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