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: 22/05/2024

Study | Ongoing

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
Ongoing

Research institution and networks

Institutions

Pfizer
First published: 01/02/2024
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Institution

MEDICAL PLUS, s.r.o. Uherské Hradišt?, Revmatologická ambulance Ostrava, Thomayerova nemocnice Prague, Revmatologický ústav Prague, RHEUMA s.r.o. B?eclav, BORMED, spol. s r.o. Ostrava-T?ebovice, Revmatologie s.r.o. Brno, Value Outcomes s.r.o

Contact details

Study institution contact
Dana Vidimova
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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921330 Final Protocol 02 April 2019.pdf(7.95 MB)

A3921330 Non Interventional Study Protocol_Amendment 1 V2_clean_18Jun2021 (2).pdf (1.96 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

Anatomical Therapeutic Chemical (ATC) code
(L04AA29) 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
154

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, 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