Association of tofacitinib with psychiatric disorders

First published: 17/12/2020

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38716

EU PAS number

EUPAS38690

Study ID

38716

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Descriptive cohort study on occurrence of psychiatric events in incident users of baricitinib, tofacitinib or tocilizumab from January 2017 to June 2020 treated for rheumatoid arthritis.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/09/2020

Actual: 24/09/2020

Study start date
Planned: 20/11/2020

Actual: 20/11/2020

Data analysis start date
Planned: 20/11/2020

Actual: 20/11/2020

Date of final study report
Planned: 10/12/2020

Actual: 10/12/2020

Sources of funding

- EMA

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To describe incidence rates of recorded psychiatric disorders occurring in association with tofacitinib, baricitinib or tocilizumab in adult patients with a diagnosis of rheumatoid arthritis (ICD 10 codes M05 and M06), To describe characteristics of adult patients with rheumatoid arthritis experiencing psychiatric events with tofacitinib, baricitinib or tocilizumab

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TOFACITINIB CITRATE

TOCILIZUMAB

BARICITINIB

Additional medical condition(s)

Mania/bipolar or severe depression, Other depression, Other mood disorder, Schizophrenia-related disorder, Suicidal and self-harm events

Population studied

Short description of the study population

The study population will include adult patients aged ≥18 years registered in the IMS® Disease Analyzer Germany database with a history of rheumatoid arthritis who are initiating treatment with baricitinib, tofacitinib or tocilizumab on or after 1 January 2017 and have at least 365 days of observation prior to the first prescription.

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

Immunocompromised

Estimated number of subjects

1891

Study design details

Data analysis plan

See section 6.7 of the report

Documents

Study results

RDA-tofacitinib_report on results.pdf(329.29 KB)

Data management

Data sources

Data source(s), other

IQVIA Disease Analyzer Germany

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