Association of tofacitinib with psychiatric disorders

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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 institution 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 data collection

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