The risk of cardiovascular adverse effects associated with JAK inhibitors in rheumatoid arthritis: a protocol for a systematic review and meta-analysis

First published: 07/12/2020

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35534

Study ID

43016

DARWIN EU® study

No

Study countries

Portugal

Study status

Finalised

Research institutions and networks

Institutions

Pharmacovigilance and Pharmacoepidemiology, AIBILI

Portugal

First published: 11/04/2011

Last updated: 01/09/2023

Institution | **Educational Institution** | **Not-for-profit** | **ENCePP partner**

Contact details

Study institution contact

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Primary lead investigator

Carlos Alves

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2020

Actual: 01/04/2020

Study start date
Planned: 01/04/2020

Actual: 01/04/2020

Date of final study report
Planned: 31/12/2020

Actual: 31/12/2020

Sources of funding

- Other

More details on funding

AIBILI

Study protocol

e041420.full.pdf (375.82 KB)

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:

Assess the risk of cardiovascular adverse effects associated with the use of JAK inhibitors in rheumatoid arthritis, as well as to explore risk variations due to risk factors, study designs and methodological quality of included studies

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

BARICITINIB

DECERNOTINIB

FILGOTINIB MALEATE

PEFICITINIB

TOFACITINIB

UPADACITINIB

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Patients diagnosed with Rheumatoid arthritis (RA) based on the American College of Rheumatology/European League Against Rheumatism criteria will be included.

Age groups

- Adolescents (12 to < 18 years)
- 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

1000000

Study design details

Outcomes

Assess the risk of all cardiovascular events with the use of JAK inhibitors in rheumatoid arthritis

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Data analysis plan

Odds ratios (ORs) and their 95% confidence intervals (CIs) will be pooled. The risk estimates will be considered statistically significant if the 95%CI do not contain the value 1. A network map linking all the pharmacological treatments will be formed.The network meta-analyses and forest-plot diagrams will be designed using a random-effects model. The inconsistency test will be conducted in order to assess the extent of disagreement between the direct and indirect evidence. A comparison-adjusted funnel plot will be used to test small-study effect and publication bias. For each outcome, treatments will be ranked according to the probability of being the safest (best) alternative using the surface under the cumulative ranking curve (SUCRA), expressed as a percentage. All the statistics will be performed using STATA (version 13.1.).

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

Estimated obtained in previously conducted studies

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