

# The risk of infections 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

Planned

## Administrative details

### EU PAS number

EUPAS35531

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### Study ID

43019

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### DARWIN EU® study

No

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### Study countries

 Portugal

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### Study status

Planned

## Research institutions and networks

## Institutions

### Association for Innovation and Biomedical Research on Light and Image (AIBILI)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Carlos Alves [calves@aibili.pt](mailto:calves@aibili.pt)

Study contact

[calves@aibili.pt](mailto:calves@aibili.pt)

### Primary lead investigator

Carlos Alves

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/04/2020

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### Study start date

Planned: 01/04/2020

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### **Date of final study report**

Planned: 31/12/2020

## Sources of funding

- Other

## More details on funding

AIBILI

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

Assess the risk of infections 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

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**Medical condition to be studied**

Rheumatoid arthritis

## Population studied

## 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)
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## Estimated number of subjects

1000000

# Study design details

## Outcomes

Assess the risk of serious infections 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.).

## Documents

## Study publications

Alves C, Penedones A, Mendes D, Batel-Marques F. Risk of infections and cardiov...

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## 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

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No