# 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

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Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/43019

**EU PAS number**

EUPAS35531

**Study ID**

43019

**DARWIN EU® study**

No

**Study countries**

☐ Portugal

**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**

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**Primary lead investigator**

Carlos Alves

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 01/04/2020

**Study start date**
Planned: 01/04/2020

**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

**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…

# Data management

## 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