# Post Marketing Safety Surveillance of Baricitinib in Three European Registries (I4V-MC-B012)

**First published:** 17/12/2018

**Last updated:** 31/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS25142

**Study ID**

25143

**DARWIN EU® study**

No

**Study countries**

- ☐ Germany
- ☐ Sweden
- ☐ United Kingdom

**Study description**

The objectives of this study are:(1) To monitor the incidence rate and profile of the following aggregate outcomes: serious infections (including herpes zoster) and opportunistic infections (including tuberculosis, Candida infections, and progressive multifocal leukoencephalopathy PML), major adverse cardiovascular events (MACE), malignancies (including lymphoma and typically virus-induced malignancies, such as cervical and many oropharyngeal cancers), and venous thromboembolism (VTE) among patients with long-term exposure to baricitinib compared to patients with long-term exposure to other medications indicated for moderate-to-severe RA, as possible given the data available in the BSRBR, RABBIT and ARTIS registries.(2) To describe the occurrence of the following individual outcomes: lymphoma, herpes zoster, opportunistic infections, rhabdomyolysis, agranulocytosis, PML, gastrointestinal perforations, and evidence of drug-induced liver injury, as possible given the data available in the BSRBR, RABBIT, and ARTIS registries.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Eli Lilly and Company

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

**Last updated:** 01/02/2024

Institution

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Salinas Claudia

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Actual: 12/05/2017

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**Study start date**

Actual: 12/05/2017

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**Date of final study report**

Planned: 31/03/2024

Actual: 19/03/2024

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Eli Lilly and Company

# Study protocol

B012 PASS Version 1.0 Nov2018_Redacted.pdf(604.46 KB)

# Regulatory

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

No

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To monitor the incidence rate and profile of the following aggregate outcomes serious infections and opportunistic infections, MACE, malignancies, and VTE among patients with long-term exposure to baricitinib compared to patients with long-term exposure to other medications for moderate to severe RA. Also to monitor the occurrence of more rare individual outcomes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

BARICITINIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA37) baricitinib

baricitinib

## Population studied

**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)

**Estimated number of subjects**

2500

## Study design details

**Outcomes**

Primary outcomes: -serious infections (including herpes zoster) and opportunistic infections (including TB, Candida infections, and PML).-MACE-Malignancies (including lymphoma and typically virus-induced malignancies such as cervical and many oropharyngeal cancers)-venous thromboembolism Secondary outcomes: -rhabdomyolysis-arganulocytosis-PML-gastrointestinal perforations-drug induced liver injury

**Data analysis plan**

Analysis of BSRBR, RABBIT, and ARTIS data is under the control of each individual registry and will not (with the exception of ARTIS) include input from Lilly. In general, each registry will provide incidence rates and outcomes and a final comparative report.

## Documents

**Study report**

LY3009104 B012 NI PASS Final Study Report_ENCePP_Redacted.pdf(4.31 MB)

# Data management

## Data sources

**Data source(s)**

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

**Data sources (types)**

Disease registry

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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