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

First published: 17/12/2018

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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.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

claudia.salinas@lilly.com

Primary lead investigator

Salinas Claudia

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/05/2017

Study start date

Actual: 12/05/2017

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

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 nameBARICITINIB

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

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 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

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Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No