An Observational Cohort Study to Investigate the Risk of Serious Infections Among Patients Exposed to Baricitinib Using the Medical Data Vision (MDV) Database in Japan (4V-JE-B019)

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Study Ongoing

Administrative details

EU PAS number

EUPAS48504

Study ID

48505

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to assess and compare the risk of SIs in the patients exposed to baricitinib with those in the patients with RA who newly started any bDMARD. The secondary objectives of the study are: * To describe incidence of SIs in elderly patients (aged ≥65 years). * To describe the incidence rates of herpes zoster.

Study status

Ongoing

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

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Primary lead investigator

Yujing Huang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/12/2020

Actual: 17/12/2020

Study start date
Planned: 01/04/2008

Actual: 25/05/2021

Date of final study report
Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly Japan K.K.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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:

The primary objective of this study is to assess and compare the risk of serious infection in the patients exposed to baricitinib with those in the patients with RA who newly started any bDMARD. The secondary objectives of the study are: To describe incidence of SIs in elderly patients (aged ≥65 years). To describe the incidence rates of herpes zoster.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OLUMIANT

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)

Estimated number of subjects

2.726

Study design details

Outcomes

The primary objective of this study is to assess and compare the risk of serious infection in the patients exposed to baricitinib with those in the patients with RA who newly started any bDMARD. The secondary objectives of the study are: To describe incidence of SIs in elderly patients (aged ≥65 years). To describe the incidence rates of herpes zoster.

Data analysis plan

For the primary objective, the analysis will be comparison of 2 hazards of incident serious infection (SI) in patients initiating baricitinib relative to a reference group of patients initiating bDMARDs using Cox proportional hazards regression models. The propensity score matching and IPTW method will be used in attempt to achieve the balance of potential confounding variables between 2 groups. For secondary objectives, the incidence rate of SI in elderly patients (aged ≥65 years) for both cohorts will be calculated. In addition, the incidence rate of herpes zoster will also be calculated and the hazard ratio of SI among baricitinib group relative to a reference group of patients initiating bDMARDs adjusting confounding factors will also be conducted . The Kaplan-Meier method will be used to display the time until patients develop the first event (event-free period).

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)

Administrative healthcare records (e.g., claims)

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