A Prospective Observational Study to Assess the Long-Term Safety of Baricitinib Compared with Other Therapies Used in the Treatment of Adults in the United States with Moderate-to-Severe Rheumatoid Arthritis in the Course of Routine Clinical Care (I4V-MC-B003)

First published: 02/04/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25139

Study ID

29470

DARWIN EU® study

No

Study countries

☐ United States

Study description

*Note, this study was terminated, and the attached final abbreviated report contains descriptive information up until time of termination. The goal of this study is to monitor the incidence and nature of key aggregate serious and opportunistic infections, MACE, malignancies and VTE amongst patients with long-term exposure to baricitinib compared to patients treated long-term with bDMARDs or cDMARDs and to describe the incidence of key individual outcomes. This goal will be achieved through the following specific objectives: The primary objectives are: 1. to compare the incidence rates and profiles of the following aggregate outcomes: serious infections (including herpes zoster) and opportunistic infections (including tuberculosis, Candida infections, and PML), MACE, malignancies (including lymphoma and typically virus-induced malignancies such as cervical and many oropharyngeal cancers), and VTE, among patients with long-term exposure to baricitinib versus patients with long-term exposure to other medications indicated for moderate-to-severe RA. 2. to describe the incidence rates of the following individual outcomes: lymphoma, herpes zoster, opportunistic infections such as tuberculosis, Candida, and PML, rhabdomyolysis, myelosuppression, (agranulocytosis), hyperlipidaemia (hypercholestoerolaemia, hypertriglyceridaemia), gastrointestinal perforations, and evidence of drug-induced liver injury. A secondary objective is to describe the incidence of the above outcomes in very elderly patients (aged ≥75 years).

Study status

Finalised

Research institutions and networks

Institutions

Corrona Rheumatoid Arthritis Registry

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Institution

Contact details

Study institution contact

Salinas Claudia claudia.salinas@lilly.com

Study contact

claudia.salinas@lilly.com

Primary lead investigator

Salinas Claudia

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/04/2019

Actual: 12/04/2019

Study start date

Planned: 31/12/2018

Actual: 31/07/2018

Data analysis start date
Planned: 22/04/2019

Date of final study report
Planned: 31/12/2031

Actual: 06/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B003 PASS Version 1.0 Nov2018_Redacted.pdf(3.24 MB)

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The goal of this study is to monitor the incidence and nature of key aggregate serious and opportunistic infections, MACE, malignancies and VTE amongst patients with long-term exposure to baricitinib compared to patients treated long-term with bDMARDs or cDMARDs and to describe the incidence of key individual outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OLUMIANT

Medical condition to be studied

Rheumatoid arthritis

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

12000

Study design details

Outcomes

The primary outcomes are: 1. the following aggregate outcomes to be evaluated in comparative analyses: serious infections and opportunistic infections, MACE, malignancies, and VTE, 2. the following descriptive outcomes: lymphoma, herpes zoster, opportunistic infections, rhabdomyolysis, myelosuppression (agranulocytosis), hyperlipidemia, GI perforations, and evidence of liver injury. To describe the incidence of the above outcomes in very elderly patients (aged ≥75 years).

Data analysis plan

Risk of each aggregate primary outcome will be compared between patients with rheumatoid arthritis (RA) treated with baricitinib and similar patients treated with (a) bDMARDs and (b)cDMARDs. Hazard ratios will be calculated based on Cox proportional hazard regression as a measure of the association between baricitinib and each comparative outcome. Propensity scores will be used to match patients between cohorts. Sensitivity analyses will examine the effect of duration of baricitinib exposure and different latency periods on risk of

malignancy. The impact of unmeasured confounding will also be evaluated. Sensitivity analyses will also investigate recurrent events such as infections using generalised estimating equation negative binomial regression models with a log link. Overall incidence rates and rates over time will be calculated separately for comparative, aggregate outcomes (primary outcomes #1 above) and less common outcomes (primary outcomes #2).

Documents

Study results

LY300914 B003 NI PASS Final Study Report v1.pdf(572.69 KB)

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)

Disease registry

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