A Retrospective Cohort Study to Assess the Safety of Baricitinib Compared with Other Therapies Used in the Treatment of Rheumatoid Arthritis in Nordic Countries (I4V-MC-B011)

First published: 15/04/2019

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS25151

Study ID

42324

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

This study aims to evaluate the safety of baricitinib among (A) rheumatoid arthritis (RA) and (B) atopic dermatitis patients treated in routine clinical care. Primary objectives: (1) to compare the incidence rates and profiles of: serious infections overall (including herpes zoster) and opportunistic infections (including tuberculosis, Candida infections, and progressive multifocal leukoencephalopathy), major adverse cardiovascular events, malignancies overall (including lymphoma and typically virus induced malignancies such as cervical and many oropharyngeal cancers), and venous thromboembolism, among patients with long term exposure to baricitinib compared to similar patients with long term exposure to other indicated medications, (2) to describe the incidence rates of the following individual outcomes: lymphoma, herpes zoster, opportunistic infections such as tuberculosis, Candida, and progressive multifocal leukoencephalopathy, rhabdomyolysis, agranulocytosis, hyperlipidaemia (hypercholesterolaemia, hypertriglyceridaemia) - RA only, gastrointestinal perforations, and liver injury. Secondary objectives: (3) to monitor the incidence rates of the aggregate outcomes of serious infections overall, MACE, malignancies overall, and VTE in very elderly patients, that is, those ≥75 years of age, (4) to assess the effectiveness of risk minimisation activities by describing the pattern of use of baricitinib and the occurrence of pregnancy, active tuberculosis or active viral hepatitis, and monitoring and treatment of lipid levels in relation to such use in routine clinical care.

Study status

Ongoing

Research institutions and networks

Institutions

Institute of Applied Economics and Health Research (ApHER)

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

Claudia Salinas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/09/2018

Actual: 13/07/2017

Study start date
Planned: 31/12/2018

Actual: 02/12/2019

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company Corporate Center

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

Drug utilisation

Main study objective:

1. To compare risk of serious infections overall, opportunistic infections, MACE, malignancies overall and VTE among RA patients treated with baricitinib vs. with other medications, 2. To describe the incidence rates of the following individual outcomes: lymphoma, herpes zoster, specific opportunistic infections, rhabdomyolysis, agranulocytosis, hyperlipidemia, GI perforations, and liver injury.

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

- 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)

Special population of interest

Pregnant women

Estimated number of subjects

12000

Study design details

Outcomes

Primary outcomes: 1. serious infections overall, opportunistic infections, MACE, malignancies overall, and VTE 2. lymphoma, herpes zoster, opportunistic infections such as tuberculosis, Candida, and PML, rhabdomyolysis, agranulocytosis, hyperlipidaemia (hypercholesterolaemia, hypertriglyceridaemia), gastrointestinal perforations, and liver injury, Secondary outcomes include the occurrence of pregnancy, active tuberculosis or active viral hepatitis and the outcomes described in primary outcomes #1 (above), but among very elderly patients (≥75 years of age) treated with baricitinib.

Data analysis plan

Risk of each aggregate primary outcomes 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. Sensitivity analyses will also investigate recurrent events such as infections. 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 report

LY3009104 B011 Non-interventional PASS Final Study Report Objective 4 (5).pdf (310.83 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 source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Swedish Rheumatology Quality Register Sweden, National Inpatient Registry Sweden, Swedish Medical Birth Registry Sweden, Swedish Population Registry Sweden, Swedish Cause of Death Registry Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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