Baricitinib Drug Utilisation Study: Assessment of Effectiveness of New Recommendations for Use Based on Secondary Data Sources in France, Germany, The Netherlands, and Sweden (I4V-MC-B038)

First published: 03/01/2024

Last updated: 17/05/2024

Study Planned

Administrative details

EU PAS number

EUPAS104431

Study ID

104432

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Sweden

Study description

Olumiant™ (baricitinib) is a selective and reversible inhibitor of Janus Kinase (JAK)1/JAK2 indicated for the treatment of moderate-to-severe active rheumatoid arthritis, moderate-to-severe atopic dermatitis, and severe alopecia areata. Following the safety review of JAK inhibitors initiated at the request of the European Commission (EC) under Article 20 of Regulation (EC) No 726/2004, EMA’s human medicines committee endorsed new recommendations by the Pharmacovigilance Risk Assessment Committee to minimise the risk of serious adverse events with JAK inhibitors. These adverse events include cardiovascular conditions, blood clots, cancer, and serious infections. EMA requested Lilly to conduct a drug utilisation study for baricitinib to assess the effectiveness of the new recommendations resulting from the Article 20 referral. These recommendations state that JAK inhibitors should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past, and those at increased risk of cancer. JAK inhibitors should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism). Furthermore, the doses should also be reduced in patient groups who are at risk of VTE, cancer, or major cardiovascular problems, where possible. Additional risk minimisation measures (aRMMs) communication channels for these recommendations include Direct Healthcare Professional Communication (DHPC), Healthcare Professional educational materials, and a Patient Alert Card (PAC).

Study status

Planned

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

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Institution | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Merola

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/03/2023

Actual: 03/03/2023

Study start date
Planned: 31/01/2026

Date of final study report
Planned: 31/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly

Study protocol

LY3009104 B038 Non-interventional PASS Protocol v0.2.pdf(1.2 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type:

Non-interventional study

Main study objective:

This study aims to describe changes in the utilisation of baricitinib in patients with RA, AA, or AD following the updated recommendations and limitations for use in the new aRMMs as a measure of prescribers' compliance. The study purpose will be met through primary objectives that will be assessed in the 12 months before and after dissemination of the DHPC.

Study Design

Non-interventional study design

Other

Study drug and medical condition

Name of medicine

OLUMIANT

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

BARICITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AA37) baricitinib

baricitinib

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

1200

Study design details

Outcomes

1. To describe characteristics of patients treated with baricitinib for RA, AA, or AD, in terms of demographics, comorbidities, and prior and current medication use.
2. To evaluate prescribers' adherence to the baricitinib aRMMs, specifically compliance to: recommended posology and duration of use recommendations for patient screening and lab monitoring recommendations for limitations of use

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Data analysis plan

All analyses will be descriptive, and results presented by indication and country, and study period, that is, before (Study Period 1) and after (Study Period 2) DHPC distribution. Changes between study periods will be summarised descriptively. No comparisons will be made across countries due to heterogeneity in coding schemes, healthcare systems, and potential differences in prescribing behaviour. Continuous variables will be summarised using the median and interquartile range while categorical variables summarised as count and proportion (%), with 95% CIs where relevant. Missing values will be

reported as missing, and no imputation attempted. Patients will be described with regards to demographics, comorbidities, disease characteristics, prior and current treatments, ADD, duration of baricitinib use and patient screening and lab monitoring. Subgroup analyses will be conducted for patients ≥65 years old, and those with ≥1 risk factor for VTE, MACE, malignancy, or serious infection.

Data management

Data sources

Data source(s)

PHARMO Data Network

German Pharmacoepidemiological Research Database

Système National des Données de Santé (French national health system main database)

Data source(s), other

Swedish Health Registers (SHR) Sweden

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