Rheumatologist and Dermatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant (baricitinib), a JAK1/2 inhibitor (I4V-MC-B025)

First published: 04/10/2021

Last updated: 21/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43239

Study ID

43240

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

United Kingdom

Study description

This study will assess: a) effectiveness of the updated baricitinib healthcare professional (HCP) educational materials and Patient Alert Card among dermatologists and rheumatologists and b) the effectiveness of a Direct Healthcare Professional Communication (DHPC) distributed to dermatologists and rheumatologists. This study was updated as a result of the Article 20 referral for JAKi, the protocol was endorsed by PRAC.

Study status

Ongoing

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kristin Meyers

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/09/2021

Study start date

Planned: 31/03/2024

Actual: 27/03/2024

Date of final study report

Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3009104 B025(b) NI PASS Protocol_Redacted.pdf(493.76 KB)

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 list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Study design:

This study uses a multi-national, observational cross-sectional design.

Main study objective:

1) assess effectiveness of updated HCP Educational Materials and PAC among dermatologists and rheumatologists. Key risk messages within these materials include those pertaining to pregnancy, infections, lipids, VTE, MACE, malignancy

and dosing. 2) The effectiveness of a DHPC distributed to dermatologists and rheumatologists.

Study Design

Non-interventional study design

Cross-sectional

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

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

400

Study design details

Outcomes

The proportion of HCPs who demonstrate understanding of the important safety information in HCP Educational Materials and in the DHPC. We will also report proportion who report communication of important safety information to their patients prescribed baricitinib for the first time and the proportion who distribute the PAC to patients prescribed baricitinib for the first time.

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for responses to questions that address the survey objectives (i.e. excluding demographic questions). Survey data will be analysed overall, and stratified by country, prescriber status (has previously prescribed baricitinib or has not previously prescribed baricitinib), and by number of patients treated.

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)

Other

Data sources (types), other

Data for this study will be collected through a survey of dermatologists.

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