Rheumatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant® (baricitinib) a JAK1/2 inhibitor (I4V-MC-B010)

First published: 01/02/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25154

Study ID

38240

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Sweden
- [ ] United Kingdom

Study description

This study will assess: a) Rheumatologists' understanding of the important safety information detailed in the Healthcare Professional Educational Material, that is, information relating to: Pregnancy and breast feeding Infections Changes in lipid parameters b) Communication of the important safety information and mitigating actions to patients prescribed baricitinib for the first time c) Distribution of the Patient Alert Card (PAC) to patients prescribed baricitinib for the first time.

Study status

Finalised

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

Claudia Salinas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2019

Actual: 03/12/2018

Study start date

Planned: 31/03/2019

Actual: 19/03/2018

Date of final study report

Planned: 30/09/2020

Actual: 17/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B010 PASS Version 1.0 Nov2018_Redacted.pdf (5.41 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 list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

a) Rheumatologists’ understanding of impt. safety information from the HCP Educational Material, i.e. information relating to pregnancy/breastfeeding, infections, & changes in lipid parameters,b) Communication of impt. safety information & mitigating actions to patients prescribed baricitinib for the 1st time,c) Distribution of the PAC to patients prescribed baricitinib for the 1st time.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

OLUMIANT

Population studied

Short description of the study population

Eligible rheumatologists who responded to the survey invitation made up the study population. Rheumatologists were expected to be the prescribing HCP in the EU Member State countries participating in this survey.

Inclusion criteria

Rheumatologists were required to meet the following criterion for inclusion in the survey:
• Must identify themselves as currently treating patients with RA and must be previous or potential prescribers of baricitinib.
To ensure that survey results adequately reflect the knowledge of the main target of the survey, at least 50% of the total completed surveys were required from those who had already prescribed baricitinib at the time of survey participation.

Exclusion criteria
Rheumatologists meeting the following criterion were not permitted to take the survey:
• Current or past employment with Eli Lilly and Company (Lilly) or any of its affiliates, United BioSource LLC (UBC), the EMA or any NCA.

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
200

Study design details

Outcomes

The proportion of rheumatologists who demonstrate understanding of the important safety information.Among prescribers, the proportion who communicate this information and mitigating actions to patients prescribed baricitinib for the first time, and who distribute the PAC to patients prescribed baricitinib for the first time.

Data analysis plan

Rheumatologists’ understanding of the important safety messages detailed in the Healthcare Professional Educational Material, communication of the important safety information and mitigating actions to patients prescribed baricitinib for the first time, and distribution of the PAC to patients prescribed baricitinib for the first time will be analysed by geography, prescribing status/number of patients treated with baricitinib, and experience with treating patients with RA.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). Stratification of results will depend on the distribution of responses to ensure that sufficient numbers are available for each stratum. Each question will be assessed individually.

Documents

Study results

Lilly EU baricitinib HCP PASS v1.0 (1)_Redacted.pdf (6.95 MB)

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 self-administered survey of rheumatologists from at least 3 countries.

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