Assessment of off-label use of baricitinib in the paediatric population (Paediatric use of baricitinib)

First published: 26/06/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS24371

Study ID

44308

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Rationale and background: Baricitinib is approved in Europe for the treatment of rheumatoid arthritis (RA) in adults. Although the potential for off-label use in paediatric patients is considered low, baricitinib has not yet been studied in children and adolescents and hence its use in this population is classified as a safety concern (missing information) in the EU-Risk Management Plan for baricitinib. Lilly has proposed this study in order to provide a more systematic evaluation of use in children and adolescents in Europe. Understanding the proportion of baricitinib prescribing that is off-label to children and adolescents will help quantitate the level of this safety concern. Research question and objectives: This study's primary objective is to evaluate the proportion of baricitinib prescribing that occurs off-label in paediatric patients (defined as less than 18 years of age). As a secondary objective, if paediatric use is ≥5 patients, this study aims to describe paediatric patients who receive a prescription for baricitinib in terms of total number of patients, demographics (age and sex) and select baseline diagnoses codes. Study design: This observational study will use a descriptive cohort design to characterize off-label prescribing of baricitinib in United Kingdom (UK) paediatric patients. Population: The setting is general care practices within the UK, limited to the practices that contribute to the Clinical Practice Research Datalink (CPRD). Patients will be retrospectively selected from the CPRD (both GOLD and Aurum) based on first occurrence of baricitinib within the database from April 2017 (date of baricitinib launch in the UK) to June 2020.

Study status

Ongoing

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Schroeder Krista

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2018

Actual: 30/06/2018

Study start date

Planned: 01/10/2019

Actual: 29/08/2019

Date of final study report
Planned: 31/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

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

Drug utilisation

Main study objective:

This study’s primary objective is to evaluate the proportion of baricitinib prescribing that occurs off-label in paediatric patients (defined as less than 18 years of age).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OLUMIANT

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- 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

50

Study design details

Data analysis plan

A descriptive approach will be used to answer the study research questions. Specifically, the total number of identified baricitinib-prescribed patients and the proportion of these patients who are younger than 18 years at index will be reported. The paediatric subgroups will be further described in terms of age (mean/standard deviation, median/ interquartile range and age categories: 0 to 5 years, 6 to 10 years, 11 to 14 years and 15 to 17 years), sex, and diagnoses (read codes) received during the 1-year pre-index (including theindex day).

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)

Clinical Practice Research Datalink

Data sources (types)

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