Comparative Assessment of VTE and Other Risks among Patients with Rheumatoid Arthritis treated with Baricitinib versus Tumor Necrosis Factor Inhibitors: A Multi-database Observational Cohort Study

First published: 17/12/2020
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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/32272

EU PAS number
EUPAS32271

Study ID
32272

DARWIN EU® study
No

Study countries
France
Sweden
United Kingdom
United States

Study description
This study aims to evaluate the safety of patients with RA treated with baricitinib. This aim will be achieved using postmarketing data from multiple sources and through the following

objectives, to be addressed by a meta-analysis of analytic results across individual data sources: Primary Objective: To compare the risk of VTE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. Secondary Objectives: • To compare the risk of MACE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. • To compare the risk of incident serious infection among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. • To describe the risk of tuberculosis (TB) requiring hospitalization among patients with RA treated with baricitinib.

Study status
Finalised

Research institution and networks

Institutions

Aetion
Spain
First published: 24/11/2022
Last updated 16/07/2024
Institution
ENCePP partner
Other

Eli Lilly and Company

Eli Lilly and Company
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

Study institution contact
Claudia Salinas
Study contact
claudia.salinas@lilly.com

Primary lead investigator
Claudia Salinas
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
12/03/2019
Actual:
12/03/2019

Study start date
Planned:
24/01/2020
Actual:
24/01/2020

Date of final study report
Planned:
31/03/2021
Actual:
30/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B023 05 Protocol(d).pdf(856.46 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Main study objective:
Primary Objective: To compare the risk of VTE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
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)

Estimated number of subjects
6000

Study design details

Outcomes
Venous thromboembolism, - MACE - incident serious infection - tuberculosis requiring hospitalization

Data analysis plan
The risk of each respective outcome will be calculated using Cox proportional hazards regression for patients with rheumatoid arthritis treated with baricitinib compared to those treated with TNFi. Results from each data source will be combined using meta-analysis.

Documents

Study results
Non interventional PASS B023 Final Study Report_Redacted_Part 1 of 6.pdf(2.11 MB)

Study report
Non interventional PASS B023 Final Study Report_Redacted_Part 2 of 6.pdf(9.51 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 3 of 6.pdf(6.11 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 4 of 6.pdf(9.5 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 5 of 6.pdf(9.5 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 6 of 6.pdf(4.27 MB)

Study, other information
Non interventional PASS B023 Final Study Report_Redacted_Part 6 of 6.pdf(4.27 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 5 of 6.pdf(9.5 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 4 of 6.pdf(9.5 MB)
Non interventional PASS B023 Final Study Report_Redacted_Part 3 of 6.pdf(6.11 MB)

Data management

Data sources

Data source(s)
THIN® (The Health Improvement Network®)
Clinical Practice Research Datalink
National Prescribed Drugs Register / Läkemedelsregistret
German Pharmacoepidemiological Research Database

Data source(s), other
Pharmetrics Plus United States, Humana United States, Aetna United States, Corrona RA Registry United States, Corrona RA Registry Japan

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Drug dispensing/prescription data

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