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

Last updated: 23/04/2024

Study Finalised

Administrative details

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 institutions and networks

Institutions

Aetion

Spain

First published: 24/11/2022

Last updated: 16/07/2024

Institution | Other | ENCePP partner

Eli Lilly and Company

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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: 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:

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

Sweden 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 healthcare records (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