Comparative assessment of venous thromboembolism and other risks among patients with rheumatoid arthritis treated with baricitinib versus tumor necrosis factor inhibitors - French part of the study program (Safety Outcomes in Patients Treated for RA)

First published: 19/03/2020

Last updated: 11/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS34204

Study ID

43731

DARWIN EU® study

No

Study countries

☐ France

Study description

Rheumatoid arthritis (RA) is a chronic autoimmune inflammatory disease characterized by progressive joint destruction, systemic complications, reduced survival, and a profoundly reduced quality of life among those affected. Baricitinib is a Janus kinase selective inhibitor indicated for treatment of moderate-to-severe RA.

Data from clinical trials demonstrate that baricitinib is an effective therapy for RA. During these clinical studies, there was a numerical imbalance in reported venous thromboembolism (VTE) between baricitinib and placebo-treated patients. However, given the limited placebo-treated patients follow-up, it was not possible to support a definitive assessment of the risk of VTE associated with baricitinib treatment, or with other outcomes such as major adverse cardiovascular events (MACE).

The baricitinib marketing authorization holder initiated an international study program to evaluate the risk of VTE, MACE, serious infection, and tuberculosis in a large number of patients treated with baricitinib or tumor necrosis factor inhibitors (TNFi) for RA in multiple country data sources. The present study aims to evaluate the safety of patients with RA treated with baricitinib in the French population, using the French nationwide claims database (Système National des Données de Santé - SNDS).

The cohort will include all patients aged >18 years with RA, who are included in SNDS and are newly treated by baricitinib or TNFi (absence of use in the 180-day period prior to cohort entry) between September 2017 and December 2019.

All patients will have a 2-year database history and will be followed until 31 December 2019 or until the first of the following events: occurrence of an event of interest, discontinuation of study treatment plus 30 days or switch to a

medication in another exposure cohort, initiation of a concomitant bDMARD or tsDMARD, health plan disenrollment, or death if identified.

Study status

Finalised

Research institutions and networks

Institutions

University of Bordeaux

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicolas Thurin

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 23/09/2019

Study start date
Planned: 01/06/2020

Actual: 08/10/2020

Data analysis start date
Planned: 01/10/2020

Actual: 13/11/2020

Date of interim report, if expected
Planned: 31/05/2021

Actual: 07/06/2021

Date of final study report
Planned: 15/12/2021

Actual: 12/01/2022

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?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

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

Drug utilisation

Main study objective:

The main objective is to compare the risk of venous thromboembolism (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

Anatomical Therapeutic Chemical (ATC) code

(L04AF01) tofacitinib

tofacitinib

(L04AF02) baricitinib

baricitinib

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AB06) golimumab

golimumab

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

5000

Study design details

Outcomes

Occurrence of venous thromboembolism VTE. Occurrence of major adverse cardiovascular events (MACE), Occurrence of serious infection, Occurrence of tuberculosis.

Data analysis plan

The following analyses will be performed: - Descriptive analyses of demographic and clinical characteristics, outcomes, drug exposure for patients with baricitinib and with TNFi.

- Comparative analyses using propensity score matching

- If the power of the study is sufficent, cox proportional hazards regression models will be used to compare the risk of an outcome among patients treated with baricitinib versus with TNFi. Any variables that remain unbalanced after propensity score matching may also be included in the regression model. Follow-up time will begin at treatment initiation and continue until censoring. Patients will be censored upon occurrence of an incident event, discontinuation of the study medication plus 30 days, the end of the study period or death.

- Sensitivity analyses to examine the effect of varying the case definition for VTE and to evaluate the existence of a class effect of Janus Kinase (JAK)

inhibitors.

Documents

Study publications

https://doi.org/10.1007/s40744-022-00505-1

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)

Administrative healthcare records (e.g., claims)

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