A Drug Utilization Study to Evaluate Indicators of Adherence to the Risk Minimization Measures for Ritlecitinib Using Electronic Healthcare Data in Denmark, France, and Sweden

First published: 21/05/2025

Last updated: 21/05/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000523

Study ID

1000000523

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France

Sweden

Study description

This is a descriptive drug utilization study using secondary data from healthcare databases in Denmark, France, and Sweden.

This study will utilize routinely collected electronic healthcare data from national or regional population-based electronic healthcare registers.

The study aims to evaluate indicators of adherence to the routine and additional routine risk minimization measures for ritlecitinib in three EU countries: Denmark, France, and Sweden.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Dominique Sighoko

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2024

Actual: 15/04/2024

Study start date

Planned: 01/09/2027

Date of interim report, if expected

Planned: 30/09/2028

Date of final study report

Planned: 31/03/2031

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

B7981102_RITLECITINIB DUS PROTOCOL_V1.0_01MAR2024.pdf(335.03 KB)

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)

Other study registration identification numbers and links

B7981102

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This will be a descriptive drug utilization study using data from healthcare databases in Denmark, France, and Sweden.

Main study objective:

The study objectives are to:

1. Evaluate, to the extent measurable in the available routinely collected data, indicators of health care professional’s (HCP) adherence to the risk minimization measures (RMMs) in accordance with the ritlecitinib SmPC, HCP guide, and Patient Card, specifically:

• Performing laboratory tests of lymphocyte count, platelet count, hepatitis B/C, and tuberculosis (TB) screening prior to initiation of ritlecitinib treatment

• Performing laboratory tests of lymphocyte count and platelet count at week 4 (± 2 weeks) from initiation of ritlecitinib treatment

• Avoiding live attenuated vaccines shortly before and during treatment with ritlecitinib

• No use during pregnancy

• No use in patients aged < 12 years

• No use during serious infections

2. Describe the characteristics of patients before initiation of ritlecitinib treatment, in terms of:

• Risk factors for thromboembolic events (including deep vein thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis)
• Risk factors for malignancy
• Risk factors for cardiovascular disease (CVD)

Study drug and medical condition

Name of medicine, other

ritlecitinib tosilate

Study drug International non-proprietary name (INN) or common name

RITLECITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AF08) ritlecitinib

ritlecitinib

Population studied

Short description of the study population

The study population will include patients identified in each data source with a record of treatment with ritlecitinib from 15 September 2023 through 14 September 2028.
Patients will not be required to have a recorded diagnosis of AA.

Study design details

Setting

Denmark, France, and Sweden have universal healthcare, whereby routinely collected data continuously accrue in the participating nationwide databases. The use of the three population-based data sources will contribute to generalisability of the study results to AA patients in the EU.

Data sources have been selected given adequate capture of some or all key study variables and relatively large underlying population sizes of patients across the regions. Indeed, the Danish, French, and Swedish databases capture information from nearly the entire populations of their residents.

These large real-world data sources are assumed to be representative of patient and physician populations in their respective countries and will provide invaluable data to evaluate measurable indicators of HCP’s adherence to the RMMs.

Outcomes

The RMMs recommend performing laboratory screening tests prior to ritlecitinib initiation, including lymphocyte count, platelet count, hepatitis B/C, and TB; performing laboratory tests of lymphocyte count and platelet count 4 weeks after initiation, avoiding live attenuated vaccines shortly before and during treatment, and avoiding use in pregnancy and during serious infections. Ritlecitinib is currently only indicated for those age 12 years or older.

- Lymphocyte count
- Platelet count
- Screening for TB
- Screening for viral hepatitis B and C
- Live attenuated vaccines
- Measles
- Mumps
- Rubella

• Others as available in data sources
• Pregnancy
• Serious infections

Data analysis plan

This is a descriptive study and the data will be analysed and results presented separately by country.

Counts and proportions for categorical variables and mean and median with ranges for continuous variables will be calculated to address the study objectives, as below. All proportions will be reported with 95% CIs.

Data sources vary in collection of laboratory test and vaccine information (data on both laboratory tests and their results are available in Denmark; data on performed laboratory tests, but not results, are available in France; laboratory data are not available in Sweden). Data on vaccines are not available in Sweden.

Counts and proportions will be calculated for:

1. Patients with evidence of having performed the following laboratory tests and screenings within 3 months before index date:
• Lymphocyte count
• Platelet count
• Screening for TB
• Screening for viral hepatitis B and C
2. Patients with evidence of having performed the following laboratory tests at week 4 (± 2 weeks) after index date:
• Lymphocyte count
• Platelet count
3. Patients with evidence of having received live attenuated vaccines within 4 weeks before index date
4. Patients with evidence of having received live attenuated vaccines during

treatment with ritlecitinib
5. Females in whom pregnancy, as recorded in the available data sources, overlaps with ritlecitinib use
6. Patients aged <12 years on the index date
7. Patients with a serious infection before index date
8. Patients with evidence of having measured risk factors and the number of measured risk factors for thromboembolic events within 12 months before index date
9. Patients with evidence of having measured risk factors and the number of risk factors for malignancy within 12 months before index date
10. Patients with evidence of having measured risk factors and the number of risk factors for CVD within 6 months before index date

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.

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

Unknown