An Active Surveillance Study to Monitor the Real-World Safety of Ritlecitinib Among Patients with Alopecia Areata in Denmark, France, and Sweden

First published: 21/05/2025

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Study Planned

Administrative details

EU PAS number

EUPAS1000000512

Study ID

1000000512

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ France
- ☐ Sweden

Study description

This is a non-interventional study (NIS) based on routinely collected electronic healthcare data from routine clinical practice aiming to actively monitor the safety events of interest following exposure to ritlecitinib, baricitinib or other approved systemic treatments for Alopecia Areata (AA) following the EU approval of ritlecitinib.

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

Study institution contact

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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: 02/07/2024

Actual: 02/07/2024

Study start date

Planned: 01/09/2027

Date of final study report

Planned: 01/03/2036

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

B7981101_RITLECITINIB SAFETY PROTOCOL_V1.0_01MAR2024.pdf (597.68 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

B7981101

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 cohort study based on prospectively collected electronic healthcare data in.
The study population will include a cohort of patients with AA initiating ritlecitinib and, to contextualize the results, cohorts of patients with AA initiating baricitinib or other systemic AA treatments.

Main study objective:
Primary objective: to estimate the incidence IRs of safety events of interest among patients with AA initiating ritlecitinib and patients with AA initiating baricitinib or other approved systemic treatments for AA in a real-world setting.

Exploratory objective: to compare the rates of the safety events of interest among patients with AA initiating ritlecitinib and patients with AA initiating baricitinib or other approved systemic treatments for AA, if study size permits.

Study Design

Non-interventional study design
Cohort

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 with AA initiating ritlecitinib, baricitinib or another approved systemic AA treatment as recorded in the participating data sources in Denmark, France, and Sweden during the cohort accrual period.

Patients will be included between 15 September 2023 until 14 September 2031 and followed through 14 September 2033.

Study design details

Setting

This study will use population-based secondary data sources from Denmark, France, and Sweden.

All three study countries have universal healthcare, whereby routinely collected data continuously accrue in the participating nationwide databases.

Loss to follow-up is expected to be minimal and primarily due to emigration, which is expected to be low.

Studies based on secondary electronic healthcare data sources are efficient for monitoring rare events and events that require long-term follow-up, when these types of events are well captured in the data source.

These large real-world data sources are expected to allow robust assessment of the safety events of interest.

Most proposed safety events of interest are likely to be well captured in the data sources, as the majority of the events require immediate treatment in

either a hospital or specialized outpatient setting.
Furthermore, safety events such as thromboembolic events have been shown to have high positive predictive values in the Danish and Swedish national registries.

Comparators

Patients with AA initiating baricitinib or other approved systemic treatments for AA, if study size permits.

Outcomes

• Thromboembolic events (including venous thromboembolism [VTE] and arterial thrombosis)
• Herpes zoster
• Serious infections
• Opportunistic infections
• Malignancy
• Malignancy excluding nonmelanoma skin cancer (NMSC)
• NMSC
• Major adverse cardiovascular events (MACE)
• Neurological events of interest
• Peripheral neuropathy
• Sensorineural hearing loss
• Migraine
• Seizures and seizure disorders
• Demyelinating disorders including multiple sclerosis
• Neurodegenerative disorders
• Bone fractures
• Growth metrics in adolescents (Denmark only)

Data analysis plan

Distributions of the characteristics of patients with AA will be reported separately for ritlecitinib and comparator groups at treatment start, using appropriate summary statistics. IRs and cumulative incidences of the safety events of interest will be computed (primary objectives) and the risks will be compared, if study size permits (exploratory objectives), between initiators of ritlecitinib and initiators of comparator AA treatments.
If conducted, measured confounding in the comparative analysis will be controlled using a propensity-score based method; unmeasured confounding will be quantified using the E-value method.

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

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No