DARWIN EU® - Characterising the use of JAK inhibitors in Europe: a Drug Utilisation Study

First published: 19/12/2024

Last updated: 15/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000424

Study ID

1000000424

DARWIN EU® study

Yes

Study countries

- [ ] Finland
- [ ] Germany
- [ ] Netherlands
- [ ] Norway

Spain

Study description

Janus kinase inhibitor (JAKi) therapy has been gaining popularity for the treatment of several autoimmune conditions, including rheumatoid arthritis, inflammatory bowel disease, and atopic dermatitis.

The first JAKi, tofacitinib, was approved by the European Medicines Agency (EMA) for the management of rheumatoid arthritis in 2017.

An FDA-requested study (the Oral Rheumatoid Arthritics Trial (ORAL) Surveillance trial) showed a higher risk of major adverse cardiovascular events (MACE), cancer and adjudicated opportunistic infection with tofacitinib compared to tumour necrosis factor (TNF) inhibitors in patients aged 50 years or older with at least one cardiovascular risk factor.

Further research has been conducted on the safety profile of JAKi for other indications, including psoriatic arthritis, ulcerative colitis and atopic dermatitis. It was shown that risk of venous thrombotic events of JAKi users was similar to placebo users in patients with atopic dermatitis and ulcerative colitis.

Incidence of adverse events, including herpes zoster infection and thrombotic events, remained similar with longer follow-up up to two years in psoriatic arthritis patients with JAKi. However, especially in these newer indications, the available evidence has been limited by short duration of follow-up and limited sample size.

The current study aims to identify the incidence of new JAKi use over time, and to characterise new users of JAKi in Europe to inform the feasibility of future safety studies.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway

☐ Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amy Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/02/2024

Actual: 06/02/2024

Study start date

Planned: 13/12/2024

Actual: 13/12/2024

Date of final study report
Planned: 30/04/2025

Actual: 22/04/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_P3-C1-001_Protocol_JAKi_V3.pdf(885.06 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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 topic, other:

JAK inhibitors

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

- Population level cohort study (objective 1)
- New user cohort study (objectives 2)

Main study objective:

1. To estimate the incidence of new JAKi use, overall and for each individual JAKi ingredient.
2. To characterise new JAKi users and treatment for each individual JAKi ingredient, over all indications and stratified by indication.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01EJ) Janus-associated kinase (JAK) inhibitors

Janus-associated kinase (JAK) inhibitors

(L04AF) Janus-associated kinase (JAK) inhibitors

Janus-associated kinase (JAK) inhibitors

Population studied

Short description of the study population

The population level cohort study will include all subjects available in the selected databases from 1st January 2017 until the most recent data lock of their respective databases, with at least 365 days of data visibility.
The patient level cohort study will include all JAKi new users from the 1st January 2017 until the most recent data lock of their respective databases, with at least 365 days of data visibility.

Documents

Study report

DARWIN EU_Report_P3-C1-001_JAKi_V2.pdf(2.68 MB)

Data management

Data sources

Data source(s)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Norwegian Health Registers

The Valencia Health System Integrated Database

Data source(s), other

FINOMOP-HILMO

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown