Non-interventional post-authorization prospective cohort study evaluating the effectiveness of the additional risk minimization measures for filgotinib (Jyseleca®) use in patients with ulcerative colitis: a European multi registry-based study

First published: 19/06/2024

Last updated: 05/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000206

Study ID

1000000206

DARWIN EU® study

No

Study countries

- [ ] Netherlands
- [ ] Spain
- [ ] Sweden

Study description

This longitudinal drug utilization study (DUS) aims to evaluate the effectiveness of the additional risk minimization measures (aRMMs) by assessing how healthcare professionals (HCPs) prescribe filgotinib for the treatment of patients with ulcerative colitis. This non-interventional, post-authorization, prospective, multi-country registry-based cohort study is being conducted based on real-word clinical data derived from 3 European inflammatory bowel disease (IBD) registries, namely the Nationwide Study on Genetic and Environmental Determinants of Inflammatory Bowel Disease (ENEIDA) Register from Spain (ES), the Initiative on Crohn's and Colitis (ICC) Register from the Netherlands (NL), and the Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG).

Study status

Ongoing

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

Alfasigma

☐ Italy

First published: 30/08/2024

Last updated: 30/08/2024

Institution **Pharmaceutical company**

Networks

ENEIDA (ES), ICC (NL), SWIBREG (SE)

Contact details

Study institution contact

Rachel Weinrib rweinrib@rti.org

Study contact

rweinrib@rti.org

Primary lead investigator

Rachel Weinrib

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/01/2023

Study start date
Actual: 25/01/2024

Date of interim report, if expected
Planned: 31/12/2027

Date of final study report
Planned: 29/03/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Study protocol

glpg0634-cl-417-protocol-redacted.pdf(5.6 MB)

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

GLPG0634-CL-417

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:

This longitudinal DUS aims to evaluate the effectiveness of the additional risk minimization measures (aRMMs) by assessing how HCPs prescribing filgotinib adhere to the updated filgotinib Summary of Product Characteristics (SmPC) and HCP Guide with a specific focus on aRMMs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JYSELECA

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

FILGOTINIB MALEATE

Anatomical Therapeutic Chemical (ATC) code

(L04AF04) filgotinib

filgotinib

Medical condition to be studied

Colitis ulcerative

Population studied

Age groups

Adults (18 to < 65 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

1500

Study design details

Outcomes

The study will include baseline and follow-up information relevant for the specific aRMM as well as information on the distribution of risk factors indicative of a high risk of major adverse cardiovascular event (MACE), venous thromboembolism (VTE), malignancy, or serious and opportunistic infections.

Data analysis plan

The patients’ baseline and follow-up characteristics will be summarized to assess adherence to the aRMMs with a focus on posology, contraindications, special warnings and precautions, monitoring, as well as the proportion of patients at high risk of major adverse cardiovascular event (MACE), venous thromboembolism (VTE), malignancy, or severe and opportunistic infections. Data will be summarized using univariable descriptive statistical methods.

Categorical variables will be summarized by number and percentage of patients in each categorical definition including 95% confidence intervals (CIs). Continuous variables will be summarized descriptively (mean, standard deviation, and median, lower quartile, upper quartile, minimum, maximum, 95% CIs). All statistical analyses will be performed by each registry or its local contracted scientific service provider.

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 source(s), other

- Estudio Nacional en Enfermedad Inflamatoria intestinal sobre Determinantes genéticos y Ambientales (Nationwide study on genetic and environmental determinants of inflammatory bowel disease) (ENEIDA), Spain
- Initiative on Crohn’s and Colitis (ICC), Netherlands
- Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG), Sweden

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