Comparative Cohort Study of Long-term Safety Outcomes of Risankizumab Compared to Biologic Treatments for Ulcerative Colitis and Crohn’s Disease in a Real-world Setting in Sweden and Denmark

First published: 01/07/2024

Last updated: 07/08/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000151

Study ID

1000000151

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Sweden

Study description

The objective is to estimate and compare, where possible, the incidence rates of malignancy excluding non-melanoma skin cancer, non-melanoma skin cancer, serious infections (including opportunistic infections), serious hypersensitivity reactions and major adverse cardiovascular events, among individuals with moderate to severe
ulcerative colitis and Crohn’s disease aged ≥18 years who initiate risankizumab in the course of routine clinical care, as well as the incidence rates in individuals who initiate other approved biologic comparator treatments for the treatment of ulcerative colitis and Crohn’s disease.

Study status

Ongoing

Research institutions and networks

Institutions

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

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Johan Reutfors

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/11/2022

Study start date

Planned: 12/10/2023

Actual: 30/05/2024

Data analysis start date
Planned: 30/06/2026

Date of interim report, if expected
Planned: 31/12/2029

Date of final study report
Planned: 31/12/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

P23654_Risa_CD-Study_abstract_Redacted.pdf (135.76 KB)

P23-654_Risa_IBD_abstract_3June2025_Redacted.pdf (102.03 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

P23-654

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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 observational cohort population-based study will be carried out using data from Sweden and Denmark.
A new-user, active comparator cohort design will be used to assess the association between exposure to risankizumab or other approved biologic treatment, with each safety outcome of interest.

Main study objective:
The objective is to estimate and compare, where possible, the incidence rates of malignancy excluding NMSC, NMSC, serious infections (including OI), serious hypersensitivity reactions and MACE, among individuals with moderate to severe UC or CD aged ≥18 years who initiate risankizumab in the course of routine clinical care, as well as the incidence rates in individuals who initiate other approved biologic comparator treatments for the treatment of UC or CD at the same line of therapy.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
SKYRIZI

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

Anatomical Therapeutic Chemical (ATC) code

(L04AC18) risankizumab

risankizumab

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Population studied

Age groups

- **Adult and elderly population (≥18 years)**

Study design details

Outcomes

The safety outcomes will be malignancy excluding NMSC, NMSC, serious infections (including OI), serious hypersensitivity reactions and MACE.

Data analysis plan

Appropriate statistical analyses in an active-comparator design will be used. Cox proportional hazards regression model will be used to evaluate the association between the exposure and each one of the safety outcomes. Crude and adjusted hazard ratios, using Inverse Probability of the Treatment Weighting, will be estimated.

Documents

Study, other information

DoI_combined_risa IBD.pdf (374.74 KB)

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Sweden National Cancer Register / Cancerregistret

Danish registries (access/analysis)

Data source(s), other

SWIBREG, Swedish National Patient Register, Swedish National Cause of Death Register, SMINET

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Pharmacy dispensing records

Population registry

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

Not applicable