An Observational Postauthorization Safety Study To Describe The Safety Of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn’s Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease (SWIBREG) (Stelara UC/CD PASS (SWIBREG))

First published: 04/01/2022

Last updated: 11/08/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS44885

Study ID

45899

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

Observational study, all drugs are prescribed (and dispensed) or administered in hospital and hospitalizations or follow-up visits registered as a part of routine medical practice.
Primary objective: evaluate the long-term safety of ustekinumab (incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis) and venous thromboembolic events), in patients treated with ustekinumab for Crohn's disease (CD) and Ulcerative Colitis (UC).
Secondary objective: compare long-term safety in CD and UC patients treated with ustekinumab and patients treated with other IBD (CD and UC) disease therapies, including TNF-alpha inhibiting (TNFi) agents or anti-integrins.

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ola Olen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2022

Actual: 20/06/2022

Study start date

Planned: 15/02/2023

Actual: 13/02/2023

Date of final study report
Planned: 31/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Pharmaceutical

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Main study objective:

To describe the long-term safety of ustekinumab for UC and/or CD, as measured by incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis TB), venous thromboembolism (VTE), major adverse cardiac events (MACE), and all-cause mortality.

Study drug and medical condition

Medicinal product name

STELARA

Medicinal product name, other

ustekinumab

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

USTEKINUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC05) ustekinumab

ustekinumab

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

8000

Study design details

Data analysis plan

The event rate of safety outcomes will be estimated for each cohort for patients using ustekinumab, TNFi, or anti-integrins.

The analysis will be performed to compare the following outcomes:

• incidence rate of malignancies

• incidence rate of infections (incl. serious infections, opportunistic infections, TB)

• incidence rate of VTEs. Incidence rates per 1,000 person-years of follow-up.

For malignancy outcomes, patients will be assigned to treatment cohorts based on a hierarchical order of exposure:

• STELARA (ustekinumab)

• TNFi biologics

• Integrin Inhibitors. The final report, as well as the interim reports, will include data on the number of patients who have entered the study in each of the treatment cohorts, cumulative follow-up time accrued in each cohort, and counts of each study outcome of interest tabulated by exposure status at cohort entry. The analysis will be performed separately for patients with CD, patients with UC and patients with IBD (UC or CD).

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

Swedish Cancer Register Sweden, Total Population Register Sweden, National Patient Register (NPR) Sweden, Infectious Disease Register (IDR) Sweden, Prescribed Drug Register (PDR) Sweden

Data sources (types)

Disease registry

Other

Data sources (types), other

Case-control surveillance database

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