An observational post-authorization safety study to describe the safety of ustekinumab and other treatments of ulcerative colitis in a cohort of patients with ulcerative colitis using the French Nationwide claims database (SNDS) France

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45589

EU PAS number

EUPAS36129

Study ID

45589

DARWIN EU® study

No

Study countries

France

Study status

Ongoing

Research institutions and networks

Institutions

University of Bordeaux

France

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/04/2020

Study start date
Planned: 31/12/2022

Actual: 31/12/2022

Date of interim report, if expected
Planned: 30/11/2025

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag International, NV

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 type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Long term safety profile of ustekinumab for UC, as measured by incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis) and VTE.

Main study objective:

The primary study objective is to describe the long-term safety of ustekinumab for UC, as measured by incidence of malignancies, infections (serious infections, serious opportunistic infections and tuberculosis), VTE, MACE and all-cause mortality The secondary study objective is to compare the long-term safety in patients treated with ustekinumab for UC and patients treated with other

therapies

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

STELARA

Medical condition to be studied

Colitis ulcerative

Population studied

Age groups

Adults (18 to < 46 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

6667

Study design details

Outcomes

Malignancies, infections and VTEs at 3-year and 5-year of follow-up:Incidence rate expressed per 1 000 patient-year in each cohort, Estimation of the cumulative incidence of each outcome in each cohort Comparison of incidence of each study outcome defined above between: ustekinumab and primary comparator, ustekinumab and secondary comparator

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Data analysis plan

Analyses will be conducted for each outcome and will include descriptive analyses, comparative analyses, and any relevant sensitivity analyses for each study cohort. Population description, comparative and sensitivity analyses will be performed at 3-year and 5-year follow-up

Data management

Data sources

Data source(s), other

SNIIRAMSNDS France

Data sources (types)

Administrative healthcare records (e.g., claims)

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