An Observational Post-authorization Safety Study to Describe the Safety of Ustekinumab and Other Crohn’s Disease Treatments in a Cohort of Patients With Crohn’s Disease

First published: 29/01/2018

Last updated: 04/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21954

Study ID

48842

DARWIN EU® study

No

Study countries

Belgium

Denmark

- France
- Germany
- Greece
- Hungary
- Ireland
- Israel
- Italy
- Netherlands
- Poland
- Portugal
- Spain
- Sweden
- United Kingdom

Study description

This is an observational, post-authorization safety study to describe the safety profile of adult patients with CD enrolled into the I-CARE study – an independent, ongoing, prospective, observational, multicenter cohort study. This study will include patients who receive ustekinumab treatment and those receiving other CD treatments within routine clinical practice, using data collected in the I-CARE study. The source population is derived from the I-CARE study, enrolling patients with CD, ulcerative colitis or IBD at sites in 16 countries across Europe. This study will focus primarily on patients enrolled into I-CARE who are being treated for CD with ustekinumab. Patients enrolled into I CARE will complete an electronic-diary on a monthly basis and an e-PRO questionnaire on a yearly basis. Additionally, a gastroenterologist will complete an annual summary at least once yearly. Patients enrolled in the study will be observed for 3 years. The final patient population of the I-CARE study will be at least 10,000 IBD patients split into 6 patient groups, with approximately 2,000 patients in the ustekinumab cohort of CD patients.

Study status

Finalised

Research institutions and networks

Institutions

Groupe d'Étude Thérapeutique des Affections Inflammatoires du Tube Digestif (GETAID)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Groupe d’Etude Thérapeutique des Affections Inflammatoires Digestives (G.E.T.A.I.D.)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ahlem Azzabi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/12/2017

Actual: 20/11/2017

Study start date

Planned: 31/12/2019

Actual: 15/12/2017

Date of final study report

Planned: 30/09/2023

Actual: 26/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Pharmaceutica NV

Study protocol

Redacted Protocol RRA-20745.pdf (2.21 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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Evaluate long-term safety of ustekinumab, as measured by the occurrence of malignancies, serious infections & VTEs associated with hospitalization, in adult patients with CD treated with ustekinumab, Evaluate risk factors for VTEs, infections and malignancies, Estimate long-term safety of adult patients with CD between users of ustekinumab and users of other CD therapies.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Secondary data analysis from prospective cohort study

Study drug and medical condition

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

USTEKINUMAB

Medical condition to be studied

Crohn's disease

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

5.115

Study design details

Outcomes

Malignancies, Serious infections (including opportunistic infections and tuberculosis TB), Events of VTE recorded with/during hospitalization.

Data analysis plan

This study will use data collected from a cohort of patients enrolled into I-CARE and who are treated with ustekinumab or other treatments for CD. The event rate of safety outcomes will be estimated for each cohort. Adverse events and serious adverse events will also be summarized. Where possible, the cumulative event rate outcomes will be estimated using time-to-event analyses, overall by cohorts and then in stratified analyses. Stratification factors (as measured at study entry) will be evaluated one at a time. For each safety outcome, risk will be compared between ustekinumab and comparators using survival analysis. Users of ustekinumab will be compared with users of anti-TNF agents and with users of immunomodulators. Study exposures will be treated as time-dependent variables. Hazard ratios will be used to estimate relative risk. A propensity score (PS) analysis will be performed to assess in an explorative manner the ‘treatment effect’ when adjusting for the potential confounders

Documents

Study results

REDACTED_CSR-Body-RRA-20745-1071569_1199308.pdf (685.61 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), other

GETAID France

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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