Retrospective non-interventional chart review study of the dosing and short-term clinical outcomes of patients with Crohn’s Disease treated with ustekinumab in Finland (FINUSTE)

First published: 06/07/2018

Last updated: 22/09/2021

Study Finalised

Administrative details

EU PAS number

EUPAS24728

Study ID

43156

DARWIN EU® study

No

Study countries

☐ Finland

Study description

The study is an observational, retrospective, non-interventional patient chart review study, whose population is adult patients with confirmed Crohn’s disease (CD) and who have initiated an intravenous ustekinumab therapy during year 2017. The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland. The secondary objectives are to determine the proportion of patients continuing treatment with ustekinumab at the time of data collection, to evaluate the change in effectiveness from baseline (measured by Harvey-Bradshaw index, endoscopic score SES-CD) at 16 weeks and at the end of study period, and to determine the reasons for ustekinumab treatment discontinuation.

Study status

Finalised

Research institutions and networks

Institutions

Helsinki University Hospital (HYKS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Helsinki University Central Hospital Meilahti unit (HYKS) Helsinki Finland, Helsinki University Central Hospital Jorvi unit (HYKS) Espoo Finland, Turku University Central Hospital TYKS Turku Finland, Tampere University Hospital TAYS Tampere Finland, Kuopio University Hospital KYS Kuopio Finland, South Carelia Central Hospital Lappeenranta Finland, Central Ostrobothnia Central Hospital Kokkola Finland, Vaasa Central Hospital Vaasa Finland, Satakunta Central Hospital Pori Finland, Kainuu Central Hospital Kajaani Finland, Päijät-Häme Central Hospital Lahti Finland, Central Finland Central Hospital Jyväskylä Finland, Lapland Central Hospital Rovaniemi Finland

Contact details

Study institution contact

Erkki Soini studies@esior.fi

Study contact

studies@esior.fi

Primary lead investigator

Taina Sipponen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/04/2018

Study start date

Actual: 02/05/2018

Data analysis start date

Actual: 05/06/2018

Date of final study report

Planned: 30/09/2019

Actual: 11/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag AB

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, non-interventional, retrospective patient chart review 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

Short description of the study population

Adult patients with confirmed Crohn’s disease (CD) and who have initiated an intravenous ustekinumab therapy during year 2017.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

80

Study design details

Outcomes

The primary outcome of the study is the ustekinumab treatment and dose adjustments (mean and median ustekinumab dose and dosing interval), Secondary outcomes include disease activity measured by Harvey-Bradshaw index, and disease activity, measured by SES-CD. Both are measured at 0 and 16 weeks and at the end of study period.

Data analysis plan

To present the observed variables, frequencies and statistical testing for each sensible comparison. To perform statistical tests on univariate comparisons, the $\chi 2$ test (for categorical data) and parametric tests, such as the analysis of

variance (ANOVA, for continuous data) are considered if the sample size is sufficient. E.g. with less than 30 observations in a group with continuous variable being compared, non-parametric tests are considered. Where feasible, point estimates with interval estimates (confidence intervals or standard errors) are presented. P-value lower than 0.050 is considered statistically significant.

Documents

Study, other information

180706_research_centres.pdf(59.73 KB)

Study publications

Eberl A, Hallinen T, af Björkesten C-G. Ustekinumab for Crohn’s disease: a nati...

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 sources (types)

Electronic healthcare records (EHR)

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