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

PURI
https://redirect.ema.europa.eu/resource/43156

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 institution 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
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Study contact

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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 data collection

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 ?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

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