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





# Administrative details

### **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



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

# 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)</li>
- Adults (65 to < 75 years)</li>
- 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