# Retrospective non-interventional chart review study of the relationship of fecal calprotectin and long-term outcomes in adult patients with Crohn's Disease to improve the quality of care in Finland (RECREFO)

**First published:** 16/01/2017

**Last updated:** 02/04/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS17190

**Study ID**

17191

**DARWIN EU® study**

No

**Study countries**

Finland

**Study description**

The study is an observational, retrospective, patient chart review study, whose population is adult patients with confirmed Crohn’s disease (CD) and who have initiated a biologic therapy at any time during the study period. The primary aim of the study is to investigate the association of fecal calprotectin (fCal) on the long-term clinical outcomes and health care resource use of CD patients. The secondary aim is to obtain a descriptive analysis of the current treatment pattern of CD patients in Finland.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Helsinki University Hospital (HYKS)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Peijas unit

## Tampere University Hospital

Finland

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

## Helsinki University Central Hospital Jorvi unit (HYKS) Helsinki, Finland, Turku University Central Hospital (TYKS) Turku, Finland, Tampere University Hospital (TAYS) Tampere, Finland

# Contact details


**Study institution contact**

Erkki Soini studies@esior.fi

Study contact

studies@esior.fi

**Primary lead investigator**

Pauliina Molander

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 29/08/2016

**Study start date**
Actual: 31/10/2016

**Data analysis start date**
Planned: 01/02/2017

**Date of interim report, if expected**
Planned: 01/03/2017

**Date of final study report**
Planned: 01/09/2017

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Janssen-Cilag

# 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 type:**

Non-interventional study

---

**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To investigate the association of fCal and the long-term course of clinical evolution and health-care resource utilization in adult CD patients.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Observational, retrospective patient chart review study

## Study drug and medical condition

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

ADALIMUMAB

INFLIXIMAB

VEDOLIZUMAB

---

**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**

150

## Study design details

**Outcomes**

The primary goal of the analysis is to associate fCal 12 months after initiation of therapy with surgery free survival over time. Primary complementary objectives are to assess the simple correlations and potentially the more comprehensive impact of fCal and surgery free survival. The secondary goal of the analysis is to associate fCal 12 months after initiation of biologic therapy with other health care resource utilization and outcomes that will affect resource utilization and to gain a description of the current CD treatment pattern in Finland.

---

**Data analysis plan**

Statistical tests on univariate comparisons are done. Estimation of the survival or treatment failure is based on suitable methods, such as univariate and multivariate hazard or multivariate survival models. Where feasible, point estimates with interval estimates (confidence intervals or standard errors) are presented. P-value lower than 0.050 is considered statistically significant.

# 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)**

Other

**Data sources (types), other**

Routine secondary care electronic patient registry

## 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