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
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/17191

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 institution and networks

Institutions

Helsinki University Hospital (HYKS)
First published: 01/02/2024
Last updated 01/02/2024
Institution

Peijas unit

Tampere University Hospital
Finland
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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

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

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