Real life management Crohn's perianal fistula (ALERT-CD)(‘a snapshot study’)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24601

Source
Nationaal Trial Register

Brief title
ALERT-CD

Health condition

Crohn's disease; Perianal fistula

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Takeda Pharmaceutical Company

Intervention

Outcome measures

Primary outcome

To assess the current management, effects on quality of life and medical costs of perianal fistula in Crohn’s disease in (routine) clinical practice in The Netherlands

Secondary outcome

- To identify treatment variation of perianal fistula between inflammatory bowel disease (IBD) centers in the Netherlands;
- To assess the variation in definition of type of fistula (simple or complex) as judged by the treating physician; including definition used for this distinction; and modality used (clinical assessment, EUS, MRI).
- To assess quality of life of CD patients with perianal fistula, during longitudinal follow-up;
- To assess direct and indirect costs of current management of CD patients with perianal fistula, including costs related to work productivity;
- To assess the patient journey of perianal fistula in CD: patient-reported delay in diagnosis; is the treatment of patients discussed in a multidisciplinary team and if so, when; distribution of patient information; the use of e-health tools (eg. IBD monitoring apps); time to start of medication / surgery; what type of surgery performed.

Study description

Background summary

This study aims to assess the current management, effects on quality of life and health care costs of perianal fistula in Crohn's disease (CD) patients in (routine) clinical practice in the Netherlands. A multinational observational cohort study (' a snapshot study') will be set up that will include patients with CD and a (persistent) perianal fistula in a participating hospital, already receiving medical and/or surgical treatment, or new onset of perianal fistula requiring treatment and/or follow-up will be assessed for eligibility.

Study objective

NA

Study design

Baseline - 3 months - 6 months - 12 months

Contacts

Public
Erasmus Medical Center
Michiel Bak

06 500 339 76
Scientific
Erasmus Medical Center

Michiel Bak

06 500 339 76

Eligibility criteria

Inclusion criteria

- diagnosed Crohn’s perianal fistula (regardless of the extent of fistulizing disease)
- age ≥18 yrs
- speak / master the Dutch language in order to comprehend study content and informed consent
- written informed consent

Exclusion criteria

- Age < 18 years
- Cryptoglandular fistula (non-CD)
- Rectovaginal fistula
- Entero-enteral fistula
- Entero-vesical fistula

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022

Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9739
Other	METC of the Erasmus Medical Center : MEC-2021-0631

Study results