Treatment of Perianal FIstulas in Crohn*s Disease: Surgical closure vs Anti-TNF

Published: 29-03-2019
Last updated: 13-01-2025

With this study we hope to improve the closure rate of perianal Crohn*s fistulas.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON48901

Source
ToetsingOnline

Brief title
PISA II-trial

Condition

- Anal and rectal conditions NEC

Synonym
Perianal fistula

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: BROAD

Intervention

Keyword: anti-TNF, Crohn's disease, perianal fistula, surgical closure

Outcome measures

Primary outcome

The primary outcome parameter is the number of patients with closed fistulas

(based on an evaluated MRI-score) after 18 months.

Secondary outcome

Secondary outcomes are disease activity by Perianal Disease Activity Index

(PDAI), quality of life and costs.

Study description

Background summary

Currently, the treatment of Crohn's patients with perianal fistulas predominantly exist of anti-TNF medication. Even though it is a very expensive drug, its efficiency has never been directly compared to surgical closure of the perianal fistula. Based on the available literature, closure of fistulas is expected in 50% of patients in the surgical closure group compared to 25% in the anti-TNF group.

Study objective

With this study we hope to improve the closure rate of perianal Crohn*s fistulas.

Study design

Multicenter patient preference model: patients with a preference for one of both treatment strategies will be treated accordingly, whereas those patients without a distinct preference will be randomized in the usual way.

Intervention

Group I: anti-TNF (seton for ± 6 weeks under anti-TNF medication in combination with immunomodulator, followed by seton removal with continuation of anti-TNF medication for ± 1 year)
Group II: Surgical closure (seton drainage , followed by advancement plasty (AF) or ligation of the intersphincteric tract (LIFT) procedure after ± 8-10

weeks, with removal of the seton under anti-TNF in combination with immunomodulator for ± 4 months)

Study burden and risks

All patients will receive one of the standard treatment approaches that are currently used for Crohn's fistulas, therefore no additional risk is associated with participating to the trial. All effort has been performed to ensure most optimal treatment, according to best available evidence and current guidelines (including drug monitoring). Since there is no experimental study-arm, there are no additional risks associated with participation. During the study, the medical staff and trial nurses will monitor the necessity of surgical interventions and hospitalisations. After 18 months all patients will undergo a MRI to score the fistula. Secondary outcome parameters (number of draining fistulas and PDAI score) will be assessed during visits to the outpatient clinic at baseline and at intervals of 6 months for the duration of the study period. Health related quality of life will be measured by the EQ-5D and IBDQ questionnaires, both will be mailed to the patients every 3 months. Data on out-of-hospital care, and productivity losses resulting from sick-leave will be retrieved from tailored patient questionnaires.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >= 18 years;- Written informed consent;- High tract (intersphincteric, transsphincteric, suprasphincteric) perianal fistula located in the upper two-thirds of the external sphincter ;- Fistula with one internal opening (based on MRI imaging). The number of external fistulas does not have to be taken into account;- Both new fistulas or recurrent active fistula (defined as any producing fistula)

Exclusion criteria

- Proctitis (defined as any active mucosal inflammation or ulcer > 5mm in the rectum);- Anorectal stenosis (defined as the impossibility to introduce a proctoscope);- Submucosal fistulas & low intersphincteric fistulas (lower one-third of external sphincter);- Rectovaginal fistula;- Multiple internal openings;- Use of Anti-TNF medication for more than 3 months;- Previous Anti-TNF medication without any effect on perianal fistulas;- Previously demonstrated allergy for anti-TNF medication. If this allergy only concerns the chimeric monoclonal mouse-antibody infliximab, the patient could be randomised for adalumimab;- Patients with a stoma;- Immunocompromised patients with a contra-indication for anti-TNF ;- Life expectancy < 2 years;- The inability of reading/understanding and filling in the questionnaires;- Dementia or altered mental status that would prohibit the understanding and giving of informed
consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2019
Enrollment:	180
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Humira
Generic name:	Adalimumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Remicade
Generic name:	Infliximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20965
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2018-002064-15-NL
CCMO	NL66176.018.18
OMON	NL-OMON20965