

The role of the Anal Fistula Plug combined with infliximab in the treatment of perianal fistula due to Crohn*s disease. -a randomised controlled trial-

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To assess the value of the Anal Fistula Plug combined with the infliximab treatment in the treatment of patients with a chronic loose seton due to perianal Crohn*s disease in terms of success rate, continence, quality of life.

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

Summary

ID

NL-OMON29741

Source

ToetsingOnline

Brief title

infixiPLUG

Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym

anorectal fistula, perianal fistula

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Cook Medical

Intervention

Keyword: Anal Fistula Plug, infliximab, Perianal fistula, recurrence

Outcome measures

Primary outcome

1. Anorectal fistula closure rate
2. Continence

Secondary outcome

1. Morbidity
2. Quality of life

Study description

Background summary

Crohn's disease is complicated by the development of fistulas in approximately one third of patients. These fistulas are often refractory to surgery and are associated with recurrent drainage and sepsis, discomfort and impaired quality of life. The techniques often used for high perianal fistulas due to Crohn's disease are loose-setons, fistulotomy and sometimes mucosal flap advancements unfortunately with disappointing results. In recent years infliximab (monoclonal antibody against TNF-alfa) was found to have positive and safe effect on the outcome of perianal fistula due to Crohn's disease and is now widely used. In the literature there are speculations on a combined medical and surgical approach to assess the problem. Recently Armstrong and colleagues reported a new biologic Anal Fistula Plug. Armstrong achieved promising results in a prospective series of 15 patients with cryptoglandular fistula treated

with the Anal Fistula Plug.

Study objective

To assess the value of the Anal Fistula Plug combined with the infliximab treatment in the treatment of patients with a chronic loose seton due to perianal Crohn*s disease in terms of success rate, continence, quality of life.

Study design

Prospective randomised controlled double blinded trial

Intervention

insertion of the anal fistula plug

Study burden and risks

Filling out four questionnaire forms before and after surgery

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Crohn*s disease

Infliximab treatment and chronic loose seton drainage > 2 months

High anorectal fistula (transsfincteric, upper 2/3 of the sfinctercomplex which is confined by the puborectal sling and the end of the anal canal)

Informed consent

Exclusion criteria

Cryptoglandular fistula

Age<18 years

HIV-positive

No internal opening found during surgery

Perianal abscesses on preoperative MRI

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	30

Type:

Anticipated

Ethics review

Approved WMO

Application type:

First submission

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

No registrations found.

In other registers

Register

CCMO

ID

NL13767.018.06