

The Anal Fistula Plug versus the mucosal flap advancement for the treatment of Perianal Fistulas.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22310

Source

NTR

Brief title

PLUG

Health condition

Perianal fistula

Sponsors and support

Primary sponsor: Academic Medical Centre

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Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Anorectal fistula closure rate;
2. Continence.

Secondary outcome

1. Morbidity;
2. Post-operative pain;
3. Sick leave;
4. Quality of life.

Study description

Background summary

Background:

Low transsfincteric fistulas less than 1/3 of the sphincter complex are easy to treat by fistulotomy with a high success rate. High transsfincteric fistulas remain a surgical challenge. Various surgical procedures are available, but recurrence rates of these techniques are disappointingly high. The mucosal flap advancement is considered the gold standard for the treatment of high perianal fistula of cryptoglandular origin by most colorectal surgeons. In the literature a recurrence rate between 0 and 63% is reported for the mucosal flap advancement. Recently Armstrong and colleagues reported on a new biologic anal fistula plug, a bioabsorbable xenograft made of lyophilized porcine intestinal submucosa. Their prospective series of 15 patients with high perianal fistula treated with the Anal Fistula Plug showed promising results.

Objectives:

To compare the Anal Fistula Plug with the mucosal flap advancement in the treatment of high perianal fistula in terms of success rate, continence, postoperative pain.

Patients and Methods:

A total of 60 patients who are planned to undergo surgery because of high perianal fistula will be included in a double blinded randomised controlled trial to compare the Anal Fistula Plug with the mucosal flap advancement. Study parameters will be anorectal fistula closure-rate, quality of life, post-operative pain, and continence.

Follow-up: Patients will be followed-up at two weeks, four weeks, 16 weeks. At the final follow-up closure rate is determined by clinical examination.

Study objective

The anal fistula plug is superior in the treatment of high transphincteric fistulas compared to the mucosal advancement flap.

Study design

N/A

Intervention

Installation of the anal fistula plug.

Contacts

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Eligibility criteria

Inclusion criteria

1. High anorectal fistula of cryptoglandular origin (transsphincteric, upper 2/3 of the sphinctercomplex which is confined by the puborectal sling and the end of the anal canal);

2. Informed consent.

Exclusion criteria

1. Age < 18 years;
2. HIV-positive;
3. Crohn's disease;
4. Malignant cause;
5. Tuberculosis;
6. Hidradenitis suppurativa;
7. Pilonidal sinus disease;
8. No internal opening found during surgery.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date: 07-06-2007

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	NL967
NTR-old	NTR994
Other	: N/A
ISRCTN	ISRCTN97376902

Study results

Summary results

N/A