

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22310

Bron

NTR

Verkorte titel

PLUG

Aandoening

Perianal fistula

Ondersteuning

Primaire sponsor: Academic Medical Centre

meibergdreef 9

1105 AZ Amsterdam

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Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Anorectal fistula closure rate;

2. Continence.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Installation of the anal fistula plug.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 07-06-2007

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL967
NTR-old	NTR994
Ander register	: N/A
ISRCTN	ISRCTN97376902

Resultaten

Samenvatting resultaten

N/A