

# The Anal Fistula Plug versus the mucosal flap advancement for the treatment of Anorectal Fistula

Published: 30-08-2006

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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 and sick leave.

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

## Summary

### ID

NL-OMON29774

### Source

ToetsingOnline

### Brief title

Plug

### 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, Mucosal flap advancement, Perianal fistula, Recurrence

## Outcome measures

### Primary outcome

1. Anorectal fistula closure rate
2. Continence

### Secondary outcome

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

## Study description

### Background summary

Low transsfincteric fistulas less than 1/3 of the sphincter complex are easy to treat by fistulotomy with a good success rate. High transsfincteric fistulas remain a surgical challenge. Various surgical procedures are available, but all of these techniques have a disappointing recurrence rate. Recently Armstrong and colleagues reported about a new biologic anal fistula plug, a bioabsorbable xenograft made of lyophilized porcine intestinal submucosa. A promising result was achieved in their prospective series of 15 patients treated with the Anal Fistula Plug.

### Study objective

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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 and sick leave.

### **Study design**

Prospective double blinded randomised controlled trial

### **Intervention**

Placement of the anal fistula plug in the tract of the anorectal fistula.

### **Study burden and risks**

burden:

Filling out four questionnaire forms before and after surgery

Risk:

No risk

benefit:

No benefit

## **Contacts**

### **Public**

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1100DD Amsterdam  
Nederland

### **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

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))  
Informed consent

### Exclusion criteria

Age<18 years;HIV-positive;Crohn\*s disease;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
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	60

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**

**ID**

CCMO

NL13652.018.06