

# Injection with Botox in the anal sphincter versus treatment with isosorbidedinitrate ointment for patients with an anal fissure. what is the most successful treatment?

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22742

### Source

NTR

### Brief title

N/A

### Health condition

Fissura ani, anal fissure.

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** healt care provider

## Intervention

## Outcome measures

### Primary outcome

Macroscopic healing of the fissure at 4 months.

### **Secondary outcome**

1. Fissure related pain;
2. treatment induced complications;
3. fissure recurrence;
4. costs.

## **Study description**

### **Study objective**

Treatment with Botox will give a better healing rate for anal fissures compared to treatment with isosorbidedinitrate ointment.

### **Study design**

1, 2, 4, 6 and 12 months.

### **Intervention**

group I: Injection of 2x 10u botulin toxin in internal anal sphincter and application of placebo ointment 6 times daily.

group II: application of isosorbidedinitrate ointment 6 times daily and injection of placebo in internal anal sphincter.

## **Contacts**

### **Public**

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## Scientific

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## Eligibility criteria

### Inclusion criteria

All consecutive patients over the age of 18 with a chronic anal fissure presenting to our surgical outpatient clinic.

### Exclusion criteria

1. Pregnancy;
2. previous anal surgery;
3. Crohn's disease;
4. systemic causes of an anal fissure.

## Study design

### Design

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

### Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2002
Enrollment:	86
Type:	Actual

## Ethics review

Positive opinion	
Date:	08-01-2009
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	NL1543
NTR-old	NTR1614
Other	: 31011972
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results