Pelvic floor therapy in the treatment of anal fissures

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26290

Source
NTR

Brief title
FIP trial

Health condition

Patients with anal fissures; fissura ani; fissuur; fissuren;

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Medisch

Intervention

Outcome measures

Primary outcome

-Healing of the anal fissure after 8 weeks of treatment.

Secondary outcome

-Healing of the anal fissure after 12 weeks of treatment.

-Recurrence of the anal fissure after 12 weeks of treatment.

-Pain during treatment

Study description

Background summary

The FIP trial (Fissura ani in Important Persons) is a multicentre, randomized controlled study which is focused on pelvic floor therapy as an intervention in the treatment of anal fissures.

Introduction:

Anal fissures are ulcers in the anoderm, that mostly are the result of the passage of hard stool. Such anal fissures are painful during defecation but the pain can last up to hours after defecation. Anal fissures are categorized as acute or chronic fissures because for each group, there is a different standard treatment.

In patients with an anal fissure there is hypertonia of the pelvic floor muscles and the internal sphincter, which results in a compromised blood flow. Decreased blood flow to any organ gives pain. Because of this pain there is a reflectory spasm of the pelvic floor which makes defecation laborious and painful.

Current treatment of anal fissures includes drug therapy and operative treatment. A meta-analysis from a Cochrane review from 2012 about anal fissures studied the effectiveness of drug therapy. The healing rate of drug therapy is 50%, whereas the recurrence rate is also 50%.

The healing rate of the operative treatment that is carried out in the Medical Centre Alkmaar ranges from 25% tot 76% based on literature. Since this a very wide range, the practical effectiveness is difficult to assess.

The treatment with the greatest healing rate is the lateral internal sphincterotomy. This has a healing rate up to 95%. This procedure involves partial division of the internal anal sphincter.

However, this procedure carries the risk of permanent fecal incontinence. Because of this risk, this procedure is preferably not carried out.

Since the healing rates of the currently used treatment options are low and the recurrence rate is high, we want to add pelvic floor therapy to the treatment of anal fissures. The patient learns to relax their pelvic floor and relearns to defecate in the proper way. By adding pelvic floor therapy we hope to improve the healing rate and diminish the recurrence rate.

Study goal:

The goal of this study is to add pelvic floor therapy to the standard treatment of anal fissures to achieve faster healing and to diminish the chance of recurrence.

Methods:

Design:

Multicentre, open label, randomized controlled study in the Medical Centre Alkmaar, Red Cross Hospital and West Fries Gasthuis.

Patient group:

Patients with an anal fissure who are at least 18 years of age.

Based upon our sample size calculation a total of 140 participants will need to be included. 70 participants with acute anal fissures and 70 participants with chronic anal fissure.

Standard treatment:

For acute anal fissure the standard treatment is: topical application of diltiazem-gel 2% twice a day on the anus combined with stool softeners.

For chronic anal fissure the standard treatment is: fissurectomy (excision) of the fissure in the operating room with injection of botulinum toxin A in the internal sphincter. Additionally, they will use stool softeners.

Intervention:

Pelvic floor therapy according to our standardized study protocol.

Acute anal fissure:

Control group:

- 35 participants

- Standard treatment: diltiazem-gel 2% and stool softeners.

Intervention group:

- 35 participants

- Standard treatment as in the control group acute anal fissure with the intervention pelvic floor therapy.

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Chronic anal fissure:
Control group:

- 35 participants

- Standard treatment: fissurectomy of the fissure in the operating room and injection of botulinum toxin A in the internal sphinctertomy and stool softeners.

Intervention group:

- 35 participants

- Standard treatment as in the control group chronic fissures with the intervention pelvic floor therapy.

Outcomes:

- Primary:

o Healing of the anal fissure 8 weeks after treatment initiation.

- Secondary:

o Pain during treatment, measured on 9 time points. Pain score will be noted based upon the VAS score.

o Recurrence of the anal fissure 12 weeks after treatment initiation.

Study objective

We believe that pelvic floor therapy is beneficial in the treatment of anal fissures compared to standard treatment alone. With pelvic floor therapy, anal fissures heal faster and have less recurrence. Patients with pelvic floor therapy will also have earlier pain relief.

Current medicinal therapy of anal fissure has a healing percentage of 50%, but also a recurrence percentage of 50% according to a Cochrane review from 2012.

Current operative procedure as is practiced in the Medical Centre Alkmaar has a healing percentage ranging from 25% to 75% according to literature.

While a lateral internal sphincterotomy currently has the highest healing percentage in the treatment of anal fissures, it also has a risk of 5% at permanent fecal incontinence. Therefor, lateral internal sphincterotomy is preferably not done in our clinic.

It is because of this risk of incontinence and the relatively small healing percentages of the other treatments that we are searching for another treatment option.

The goal of this study is to assess the potential benefit of pelvic floor therapy in the treatment of anal fissures.

Study design

Follow-up at: 8 and 12 weeks after treatment initiation

Pain: 9 timepoints during treatment

Intervention

Controlgroup: standard treatment
Interventiongroup: standard treatment + intervention pelvic floor therapy

Standard treatment for acute anal fissure: diltiazem-gel with stool softeners

Standard treatment for chronic anal fissure: fissurectomy with botulinum toxin a injection and stool softeners

Contacts

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Eligibility criteria

Inclusion criteria

-Patients who are 18 years old or older

-Patients with an anal fissure

Exclusion criteria

-History of inflammatory bowel disease

-History of surgical interventions for anal fissure.

-History of HIV/AIDS

-Anal abscess or fistulae

-Anal fissures with low sphincter tension

-Malignant disease

-Patients using chronic pain medication

-Patients with a traumatic anal fissure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	140
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40264
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4143
NTR-old	NTR4287
CCMO	NL45145.094.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40264

Study results