Pelvic floor therapy in the treatment of all anal fissures; a multicentre, randomized controlled trial

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To assess the potential benefit of pelvic floor therapy for anal fissure. Measured primarily in pain, measured by the VAS score. Secondary outcomes are healing rates and recurrence.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON40264

Source
ToetsingOnline

Brief title
FIP-trial

Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
anal tear, anal ulcer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anal fissure, healing, pain relief, pelvic floor therapy

Outcome measures

Primary outcome

The primary outcome is pain. Pain will be measured by the VAS score. Patients are asked to draw a vertical line on a horizontal line of exactly 10 centimeters long. That line will only be number on the left side, with a 0 and on the right side with a 10. After participants have drawn their line, the researcher will measure in millimeters what their score is.

Measurement moments are baseline and after treatment starts on day 1, 2, 3, and after 1, 2, 4, 8 and 12 weeks.

Mean score will be compared between intervention and controlgroup

Secondary outcome

Secondary outcome is healing after 8 weeks. Healing will be assessed by the surgeon. Healing is defined as closure of the anal fissure.

Secondary outcome is whether or not the fissure is still healed after 12 weeks. This will again be assessed by the surgeon. Healing is defined complete closure of the anal fissure.

Portion of healed fissures will be compared between intervention and

controlgroup.

Study description

Background summary

Anal fissures are ulcers in the anoderm, that mostly are the result of the passage of hard stool. Because of the hypertonia of the pelvic floor muscles and high pressure of the internal sphincter, the blood flow is compromised, resulting in a delay of healing and an increase in pain.
Therapy is based on relaxing the internal sphincter and this can be achieved in different ways. Current non-surgical therapy have smaller success rates compared to lateral internal sphincterotomy (LIS) in terms of healing and recurrence. However, LIS, is only an option to be considered after failure of medical therapy because of the risk of permanent fecal incontinence. Since current treatment options are unsatisfactorily in healing a fissure, it*s our opinion that other possible therapies without risk of incontinence should be pursued.
We believe that an anal fissure can be successfully treated with pelvic floor therapy. Pelvic floor therapy relaxes the pelvic floor musculature and decreases the internal sphincter tension, thereby restoring blood flow to the anal fissure. It is therefore our hypothesis that pelvic floor therapy increases the success rates in the treatment of anal fissures, in terms of earlier pain relief, greater healing percentages and less recurrences. To our knowledge, this has never been investigated before.

Study objective

To assess the potential benefit of pelvic floor therapy for anal fissure.
Measured primarily in pain, measured by the VAS score. Secondary outcomes are healing rates and recurrence.

Study design

Multicentre, stratified block-randomisation, non-blinded, parallel-group, superiority designed study

Intervention

Pelvic floor therapy. Consisting out of a weekly course for 3 weeks. Each session takes about 30 minutes. General queries are asked to evaluate the pelvic floor and general information is given about how the pelvic floor should function. After that, relaxation exercises are given so that patients learn to control their pelvic floor better and in turn, learn how to relax their pelvic

floor muscles.

Study burden and risks

The burden associated with participation are extra in-hospital visits. For acute anal fissure, participants have 3 in-hospital visits (first appointment for diagnosis, then 2 follow-up appointments). For chronic anal fissure, participants have 4 in-hospital visits (first appointment for diagnosis, second appointment for surgery + botulinum toxin injection in day care, and 2 follow-up appointments). Compared to usual care, this means one extra follow-up appointment.

During the initial appointment and follow-up, participants will be questioned and physically examined (inspection of the anus). Measurement of pain through VAS scores can be managed at home and will take only a minute or so. Measurement moments will be baseline and after treatment starts: day 1, 2, 3, 7 and weeks 2, 4, 8 and 12. In the 9th week, patients will return to clinic, where they*ll be questioned and physically examined. In the 13th week after treatment initiation patients will again return to clinic, for final questioning and physical examination.

During the in-hospital visit in the 9th week, participants will be asked to fill in a short questionnaire to evaluate how they experienced pelvic floor therapy. This will take them only 5 minutes.

The burden associated with the investigational treatment pelvic floor therapy will be a weekly course for 3 weeks. One sessions will last about 30 minutes. Pelvic floor therapy will be given by certified pelvic floor therapists. There are no risks associated with pelvic floor therapy. Pelvic floor therapy provided in this study is without financial cost to the participant.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients, at least 18 years of age or older with an acute or chronic anal fissure

Exclusion criteria

Inflammatory bowel disease, malignancy, HIV/AIDS, Anal abscess or fistulae, low sphincter tension, previous surgical intervention for anal fissure, 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2014
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	25-03-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26290
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45145.094.13
OMON	NL-OMON26290