

Pelvic floor physiotherapy in treatment of Chronic Anal Fissure (PAF-study)

No registrations found.

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

Summary

ID

NL-OMON27503

Source

NTR

Brief title

PAF

Health condition

chronic anal fissure
pelvic floor dysfunction
dyssynergia
treatment
chronische anale fissuur
bekkenbodemdysfunctie
dyssynergie
behandeling

Sponsors and support

Primary sponsor: Proctos Clinics Bilthoven
Leiden University Medical Center

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

VAS-scores(pain)

Quality of life

Secondary outcome

- Prevalence of pelvic floor dysfunction in chronic anal fissure measured by physical examination and balloon expulsion test
- Difference in EMG signals of the pelvic floor before and after treatment;
- Relation between chronic anal fissures and other pelvic floor dysfunctions;
- PROM before and after PFMT

Study description

Background summary

The PAF-study is a randomized controlled study which is focused on the efficacy of treatment of chronic anal fissure and concomitant pelvic floor dysfunction with pelvic floor physiotherapy including biofeedback and/or electrostimulation.

A chronic anal fissure is a painful problem involving a tear or ulcer in the epithelium of the anus which exists longer than six weeks. Chronic anal fissure is conservatively treated, aimed at relaxation of the internal anal sphincter and normalization of the defecation pattern.

At this moment patients are treated with local ointments like isorbide nitrate or diltiazem. Furthermore, a fibre enriched diet, extra fluids, laxatives are advocated. In 90% of patients complaints will resolve after 3 months with this regime. However in 10% of patients, anal fissure does not heal, becomes inflamed and fibrotic. In those cases, local botulinum toxin injections and lateral internal sphincterotomy (LIS) and/or fissurectomie are the next step. However, lateral internal sphincterotomy has a potential hazard of incontinence (5% to 31%). Nonetheless, lateral internal sphincterotomy is currently the standard of care for surgical treatment of fissures.

Botulinum toxin is used as an effective treatment modality for anal fissure. It is considered as a minimal invasive procedure with minor adverse effects and good success rate. However, side effects include flatus and fecal incontinence, sometimes permanent.

A proportion of patients with chronic anal fissure have a history of constipation and obstructed defecation. Consequently, these patients have complaints of excessive straining, incomplete evacuation, and hard stools together with infrequent stooling.

One of the causes could be pelvic floor dysfunction as a contributing factor. A non-relaxing pelvic floor and/or pelvic floor dyssynergia result in an increase in the anorectal angle, prohibiting the normal passage of stool.

Dyssynergia is characterized by a failure of the abdominal-, rectal-, pelvic floor- and anal sphincter muscles to effectively coordinate and complete the process of defecation.

Dyssynergia is diagnosed by a validated measurement instrument, rectal balloontest and rectal examination of the pelvic floor muscles.

Dyssynergia can be effectively treated by pelvic floor physiotherapy including biofeedback therapy and/or electrostimulation. Effects of treatment of pelvic floor dysfunction on healing of a chronic anal fissure is currently unknown in literature.

We hypothesize that treatment with pelvic physiotherapy in patients with a chronic anal fissure and concomitant pelvic floor dysfunction will result in an improvement of quality of life.

We also aim to provide a management protocol for Pelvic floor physiotherapy in the treatment of chronic anal fissure.

Finally, short- and long term outcome of treatment of a chronic anal fissure using this regime will be described.

Study objective

We hypothesize that treatment with pelvic physiotherapy in patients with a chronic anal fissure and concomitant pelvic floor dysfunction will result in an improvement of quality of life.

We also aim to provide a management protocol for Pelvic floor physiotherapy(PFMT) including biofeedback with EMG in the treatment of a chronic anal fissure.

Study design

T0 start treatment

T1 after 8 weeks treatment groupA

T2 after 20 weeks after treatment groep B

T3 after one year follow up

Pain 4 timepoints

SF36 4 timepoints

PROM 4 timepoints

Intervention

Interventiongroup Pelvic Floor Physiotherapy (PFMT)including biofeedback following a standardized treatmentprotocol

Controlgroup: delayed PFMT including biofeedback following a standardized treatment protocol

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- All patients > 18 years old
- Chronic anal fissure(anal fissure existing longer than 6 weeks) and pelvic floor dysfunction

Exclusion criteria

- Patients presenting an abscess or fistula
- Patients with Crohn's disease or ulcerative colitis;
- Patients who received prior anal radiation therapy;
- Patients with diagnosed anorectal malignancy

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): | 01-12-2018 |
| Enrollment: | 133 |
| Type: | Anticipated |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 25-10-2018 |
| 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

NTR-new

NTR-old

Other

ID

NL7373

NTR7581

: P18.090 P1a

Study results

Summary results

no