Pelvic Floor Physiotherapy in chronic anal fissure

Published: 12-10-2018
Last updated: 11-04-2024

Efficacy of treatment with biofeedback assisted pelvic floor physiotherapy using electromyography (EMG) in patients with chronic anal fissure.

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

Summary

ID

NL-OMON50721

Source
ToetsingOnline

Brief title
PAF

Condition

- Anal and rectal conditions NEC

Synonym
anal gap

Research involving
Human

Sponsors and support

Primary sponsor: Proctos Kliniek Bilthoven
Source(s) of monetary or material Support: Nederlandse Vereniging voor bekkenfysiotherapie en Bekkenproblematiek(NVFB)

Intervention

Keyword: chronic anal fissure, dyssynergia, pelvic floor dysfunction, pelvic floor physiotherapy

Outcome measures

Primary outcome

- The tone at rest during EMG registration of the pelvic floor before and after therapy

Secondary outcome

- Prevalence of pelvic floor dysfunction in chronic anal fissure measured by physical examination, balloon expulsion test
- Relation between anal fissure and other pelvic floor dysfunctions
- Proctoprom at the start of the study, after 8 weeks, 20 weeks and one year follow up
- Difference in EMG signals of the pelvic floor after pelvic floor physiotherapy for tone at rest, MVC and Endurance at the start of the study, after weeks, 20 weeks and one year follow up
- Quality of life as measured by scores of the domains of the RAND-36 questionnaire, at the start of the study, after 8 weeks, 20 weeks and one year follow up
- The efficacy of PFPT with biofeedback and/or electro stimulation
- VAS- pain score at the start of the study, after 8 weeks, 20 weeks and one year follow up

Study description

Background summary

A chronic anal fissure is a painful proctological problem with a persistence of 6 weeks or more. Patients with an anal fissure usually experience pain during and immediately after defecation. The etiology of anal fissures and pain is has not been fully elucidated. Patients with anal fissure often have raised resting pressures in the anal canal with concomitant anal spasm. In literature first line treatment for anal fissures consists of conservative treatment with ointment and laxatives. When conservative treatment fails the next step can be botox injections or lateral internal sfincterotomy (LIS). A large percentage of the patients with chronic anal fissures experience also pelvic floor dysfunctions.

Study objective

Efficacy of treatment with biofeedback assisted pelvic floor physiotherapy using electromyography (EMG) in patients with chronic anal fissure.

Study design

All patients >18 years old presenting with a chronic anal fissure and pelvic floor dysfunction are eligible for inclusion after signing informed consent. Upon inclusion, demographic characteristics will be collected including age, gender, length and weight and relevant history. Clinical data will be collected including previous treatment, duration of symptoms and findings on clinical examination regarding fissure and pelvic floor dysfunction. Quality of life using validated questionnaires using SF36, VAS pain score, Rome III classification of obstipation and Altomare are also scored.
EMG-signals of the pelvic floor before, during and after pelvic physiotherapy are measured with an intra-anal probe (Maple®)
Patients with chronic anal fissure will be included and, by a computer generated list, randomly assigned to an intervention group(A), which received 8 weeks of PFPT with the MAPLe®, or into a control group whith delayed PFPT wich will start 8 weeks after inclusion.
After 8 weeks of treatment of group A both groups will be compared. (flowchart).
Patients in both groups are given an explanation of relevant anatomy and (patho-) physiology of anal fissure and the relationship with pelvic floor dysfunction and are given toilet behaviour and lifestyle instructions at the start of the study. Lifestyle changes will be focused on regulation of the defecation pattern such as the management of fluid intake and fibres. Patients will be analysed at inclusion and after 8 weeks follow-up by an experienced pelvic floor therapist to determine the effect of PFPT on QoL and pain

scores(VAS) with a structured quantitative and qualitative examination.
Besides the SF36, VAS and PROM, a EMG registration of the pelvic floor with the MAPLe will be used. The MAPLe will be placed intra-anal, with the reference electrode placed on the spina iliaca anterior superior. Patients are asked to perform three consecutive tasks: one minute rest, where patients are instructed to feel the pelvic floor in rest, ten maximum voluntary contractions (MVCs), where patients are
instructed to perform a controlled contraction and relaxation of the PFM, and three endurance contractions, where patients are instructed to contract the PFM at such a level that they could hold for 30 s. From these EMG measurements, mean EMG amplitudes per electrode are calculated. During these examinations no instructions are given on how to perform a pelvic floor muscle contraction.
Patients receive seven 30-min sessions in a period of 3 months.
The first visit and control at 8, 20, 52 weeks follow-up will be performed by the same experienced investigator(pelvic floor therapist). Treatment following the first visit will be performed by experienced pelvic floor physiotherapist using a standardised treatment protocol near patient*s residence.
This standardized treatment protocol consists of biofeedback guided exercises comprising rest, maximal voluntary contraction (MVCs), and endurance, according to the same principle during intake. Besides this, relaxation and coordination exercises combined with abdominal breathing are given. Visual feedback of the EMG signals plus verbal instruction, and reinforcement will be used to teach patients how to control the pelvic floor muscles, while keeping the abdominal muscles relaxed. The treatment was individualized to match the patient's ability and specific needs; in case of hypertonicity of the PFM the focus is more on relaxation, in case of dyssynergia the focus was more on how to relax the pelvic floor during squeezing and coordinate the abdominal muscles. If patients are unable to contract or to relax, electro stimulation will be applied intra-anally in one or two 30-min sessions to gain awareness of the PFM.
Patients will receive the assignment to exercise the taught techniques at home in between sessions while in the supine, seated, and upright positions and to integrate these techniques into their daily activities.
During the study period all data will be collected in a database. Patients will be identified with a number.

Intervention

Rectal toucher/exam and biofeedback with an anal probe.

Study burden and risks

NA

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

all patients above 18 years old with a chronic anal fissure with pelvic floor dysfunction

Exclusion criteria

Patients presenting with perianal abces or fistula
Patients presenting with Chrohns disease or colitis ulcerosa
Patients who received prior anal radiation therapy
Patients with anorectal malignancy

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:	Recruitment stopped
Start date (anticipated):	10-12-2018
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	Maple
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	31-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL65658.058.18