

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

Gepubliceerd: 25-10-2018 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27503

Bron

Nationaal Trial Register

Verkorte titel

PAF

Aandoening

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

Ondersteuning

Primaire sponsor: Proctos Clinics Bilthoven
Leiden University Medical Center

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VAS-scores(pain)

Quality of life

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Controlgroup: delayed PFMT including biofeedback following a standardized treatment

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	133
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7373

Register

NTR-old

Ander register

ID

NTR7581

: P18.090 P1a

Resultaten

Samenvatting resultaten

no