

# pelvic floor physiotherapy in treatment of anal fissure (PAF-study)

Published: 09-03-2018

Last updated: 12-04-2024

The effect of pelvic floor physiotherapy with biofeedback in patients with anal fissure and pelvic floor dysfunction.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Anal and rectal conditions NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON46466

### Source

ToetsingOnline

### Brief title

PAF: PAF: pelvic floor physiotherapy in treatment of anal fissure

## Condition

- Anal and rectal conditions NEC

### Synonym

anal fissure

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anal fissure, dyssynergia, pelvic floor physiotherapy, treatment

## Outcome measures

### Primary outcome

SF36, macroscopic healing of fissure

### Secondary outcome

pain score, PROM, score, EMG measurement of the pelvic floor

## Study description

### Background summary

Anal fissure is a painful common disease sometimes leading to a debilitating condition. Treatment of chronic anal fissure with current methods is disappointing

### Study objective

The effect of pelvic floor physiotherapy with biofeedback in patients with anal fissure and pelvic floor dysfunction.

### Study design

prospective, randomized, crossover study

### Study burden and risks

none

## Contacts

### Public

Academisch Medisch Centrum

De Boelelaan 1118  
Amsterdam 1007MB  
NL

### Scientific

Academisch Medisch Centrum

De Boelelaan 1118  
Amsterdam 1007MB  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

all patients between 18 and 75 years with an anal fissure in combination with pelvic floor dysfunction

### **Exclusion criteria**

patients presenting with perianal abscess or fistula

patients with Crohn's disease or colitis ulcerosa

patients who refuse to be submitted to endo anal or transperineal ultrasonography

patients who received prior radiation therapy

patients with diagnosed anorectal malignancy

patients with cognitive problems or difficulties in understanding dutch language

## **Study design**

### **Design**

Study type: Observational non invasive

Intervention model: Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

## Ethics review

Not approved	
Date:	09-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL64785.029.18