

# Use of laser in the treatment of perianal fistulas (Anorectale fistel laser studie = ArFiLaS)

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Anal and rectal conditions NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON45281

### Source

ToetsingOnline

### Brief title

ArFiLaS

### Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

### Synonym

peri anal fistula

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

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

## Intervention

**Keyword:** Laser, Perianal fistula, Treatment

## Outcome measures

### Primary outcome

Recurrence rate

### Secondary outcome

quality of life, post operative pain and incontinence

## Study description

### Background summary

Perianal fistulas are a common disorder, estimated to occur in 12.3 per 100.000 men and 8.6 per 100.000 woman.

Symptoms caused by a perianal fistula are pain and involuntary loss of gas, fluids or faeces. Besides these symptoms, complaints of itching and symptoms of infections are reported. These complaints often result in social embarrassment and loss of quality of life.

The mucosal advancement flap is considered as one of the best surgical treatments for high perianal fistula repair. This technique is based on closure of the internal opening of the fistula tract. In one out of three patients mucosal flap repair fails. Possible factors for failure are incomplete clearance of pus and debris, incomplete closure of the internal opening or other technical failures, or inappropriate host response in patients with risk factors like smoking or diabetes. Besides a high recurrence rate, the mucosal advancement flap is also associated with impaired incontinence, rates have been described as high as 35%.

Laser treatment is a new technique in the treatment for perianal fistulas which claim to result in none or only minimal damage to the sphincter muscles. Preliminary results show a closure rate ranging from 71,4% -89%. Until now, studies are small (n= 11 - 50) and no validated questionnaires were used to objectively assess continence and quality of life.

### Study objective

Our hypothesis is that treatment of peri-anal fistula with laser ablation is

associated with equal closure rates compared to current therapies.  
As secondary outcome, quality of life, postoperative pain and incontinence will be assessed.

The primary objective of this study is to investigate the efficacy of laser treatment in perianal fistula healing.

Primary Question:

What is the healing rate of laser-ablation in high single tract perianal fistulas?

Secondary Question(s):

Quality of life

Post operative pain

Functional outcome and risk of incontinence

## **Study design**

In this prospective multicentre cohort study we will evaluate 100 patients with high single tract perianal fistulas, who underwent laser ablation.

Hereby we want to evaluate the treatment with laser, it will be a pilot study.

All patients will receive the same treatment, which consists of a seton procedure followed by laser-ablation in a secondary procedure.

The primary endpoint of this study is healing rate. The fistula will be considered healed if the external opening is closed and no discharge or pain or perianal swelling is experienced. Recurring of these symptoms was defined as a recurrent fistula. Treatment failure is defined if there is still discharge coming out of the external opening at 3 months follow-up. Symptoms / visible fistula at another location are considered as a new primary fistula.

Secondary endpoints are quality of life, postoperative pain and incontinence, which will be assessed using the SF-12 questionnaire, a visual analogue pain scale (VAS) and the Vaizey and FIQL score.

Follow-up is planned at 6, 12, 24 and 52 weeks postoperatively. (fig 3).

Questionnaires are completed preoperatively and during all follow-up moments.

During the follow-up moments an independent colorectal surgeon will examine patients and determine if the fistula is persistent or healed. In case of doubt a new MRI-scan will be performed

## **Intervention**

Laser-ablation of the perianal fistula

## Study burden and risks

No extra risks are expected. However, there is a small risk of infection, burnwounds or technical failure of the laserfibre (kinking or break down of the fibre)

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- age: 18 \* 80 years
- able to understand informed consent
- primary fistula
- high trans- and intersphincteric fistulas

- one fistula tract, no secondary tracts, proven with MRI

## Exclusion criteria

- pregnancy
- local malignancy
- Crohn\*s disease or ulcerative colitis
- a traumatic or iatrogenic lesion

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 100

Type: Anticipated

### Medical products/devices used

Generic name: Laser

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 27-12-2017

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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: 28231

Source: NTR

Title:

### In other registers

<b>Register</b>	<b>ID</b>
CCMO	NL60042.068.17
Other	Volgt nav goedkeuring NTR
OMON	NL-OMON28231