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

Published: 27-12-2017
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	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 of 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 secundairy 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.
Al 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 assed using the SF-12 questionnaire, a visual analogue pain seal (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 al 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

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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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60042.068.17
Other	Volgt nav goedkeuring NTR
OMON	NL-OMON28231