Use of laser in the treatment of perianal fistulas

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28231

Source
Nationaal Trial Register

Brief title
ArFiLaS

Health condition

Peri-anal fistula
Laser ablation
Laser treatment

Sponsors and support

Primary sponsor: Academisch ziekenhuis Maastricht
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

healing rate

Secondary outcome

Quality of life

Post operative pain

Functional outcome and risk of 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 infection are reported. These complaints often result in social embarrassment and loss of quality of life.
The mucocal 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 of 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.

Our hypothesis is that treatment of perianal 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.

Study objective

Perianal fistulas are a common disorder, estimated to occur in 12.3 per 100.000 men and 8.6 per 100.000 woman.1 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.

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%.12-14 Until now, studies are small (n= 11 - 50) and no validated questionnaires were used to objectively assess continence and quality of life.

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Study design

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.

Secondary endpoints are quality of life, postoperative pain and incontinence.
Patients will be asked to grade their pain on a visual analogue scale (VAS: 0 no pain; 10 worst imaginable pain). Quality of life will be evaluated using the SF-12 questionnaire and the FIQL questionnaire. Continence will be evaluated using the Vaizey and FIQL score.

Follow-up is planned at 6,12, 24 and 52 weeks postoperatively. Questionnaires are completed preoperatively and during al follow-up moments.

Intervention

For this procedure we will use a 1470nm diode laser -10W. A wavelength of 1470nm allows the fistula to shrink with the use of less power, thus reducing the potential damage of tissue around the tract

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2018
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 12-10-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45281
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6713
NTR-old	NTR6892
CCMO	NL60042.068.17
OMON	NL-OMON45281

Study results