Use of laser in the treatment of perianal fistulas

Gepubliceerd: 12-10-2017 Laatst bijgewerkt: 15-05-2024

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...

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

Samenvatting

ID

NL-OMON28231

Bron
NTR

Verkorte titel
ArFiLaS

Aandoening

Peri-anal fistula
Laser ablation
Laser treatment

Ondersteuning

Primaire sponsor: Academisch ziekenhuis Maastricht
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

healing rate

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

R. Wouda
Maastricht
The Netherlands
0613232756

Wetenschappelijk

R. Wouda
Maastricht
The Netherlands
0613232756

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

pregnancy

local malignancy

Crohn’s disease or ulcerative colitis

a traumatic or iatrogenic lesion

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45281
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten