Feasibility study of Smooth Seton placement in patients with perianal fistulas

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With this study we aim to determine the feasibility of Smooth Seton placement in patients with perianal fistulas

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON42252

Source
ToetsingOnline

Brief title
Smooth Seton feasibility studie

Condition

- Anal and rectal conditions NEC

Synonym
perianal fistula

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: perianal fistula, Smooth Seton

Outcome measures

Primary outcome

The primary outcome is seton failure (loosening of the seal)

Secondary outcome

Secondary outcomes are time of procedure, complications and quality of life

measured by the the PDAI (*Perianal Disease Activity Index*).

Study description

Background summary

Perianal fistulas are a common incapacitating problem. Many patients are treated by seton drainage to prevent recurrent abscess formation. Nowadays, vesselloops or sutures are used. The knot of these seton drains can cause complaints of pain or tenderness if it presses against the external opening of the fistula or even slides in to the fistula tract. Medishield designed a knotless seton drain, the Smooth Seton. This could decrease the pain complaints caused by the knot.

Study objective

With this study we aim to determine the feasibility of Smooth Seton placement in patients with perianal fistulas

Study design

Feasibility study

Intervention

The Smooth Seton will be placed at the outpatient clinic in patients with already a seton in situ. This seton will then be exchanged by the Smooth Seoton.

Study burden and risks

The Smooth seton will be placed in patients with perianal fistulas who already have a seton in situ. There are no additional risks involved. The seton will be placed at the outpatient clinic. The material that is used for the Setons is of medical grade polyurethane, is the same material of catheters that are already used in clinical practice (instech BTPU 027). The Setons including the insert (BTPU) are supplied sterile (Synergy Health). Despite the fact that the new used seton placement system of MediShield does not come into contact with the patient, there has been a risk assessment for use of the Setons and the deployment mechanism. The system has been tested and assessed by the SBI / DH & T. In the risk analysis no scenarios that pose a potential danger to the patient.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients >= 18 years
- Written informed consent
- Perianal fistulas (for which a seton was placed that is still in situ)

Exclusion criteria

- Patients with a pacemaker or an ICD in situ
- Patients participating in a different trial
- Rectovaginal fistula
- Patients with a stoma
- Life expectancy < 2 years
- The inability of reading/understanding and filling in the questionnaires
- Dementia or altered mental status that would prohibit the understanding and giving of informed
Consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Smooth Seton
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	02-07-2015
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	NL51710.018.14