Pilot Study of SuperSeton Placement in Patients with Perianal Fistulas

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With this study we aim to determine the feasibility of SuperSeton 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-OMON45970

Source
ToetsingOnline

Brief title
SuperSeton Pilot Study

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, SuperSeton

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary outcome is seton failure

(loosening of the seton).

Secondary outcome

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

measured by 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, vessel loops or sutures are used for drainage. 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 B.V. designed a knotless seton drain, the SuperSeton. This could decrease the pain complaints caused by the knot.

Study objective

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

Study design

The design of the study is a feasibility study.

Intervention

The SuperSeton will be placed at the outpatient clinic in patients that already have a seton in situ. This seton will then be exchanged by the SuperSeton. In case patient do not have a seton in situ, the SuperSeton can be placed at the operating theatre in day care setting instead of a regular seton.

Study burden and risks

The SuperSeton will be placed in patients with perianal fistulas (with or without a seton in situ). There are no additional risks involved. The seton will be placed at the outpatient clinic in patients with a seton in situ, or at the operating theatre in day care setting in patients with a perianal abscess without a seton. 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).

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

- Patients of 18 years or older
- Written informed consent

- Perianal fistulas for which a seton was placed that is still in situ or recurrent perianal fistulas (ever treated with a knotted seton) for which a new seton will be placed

Exclusion criteria

- Patients with a pacemaker or an ICD in situ
- 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
- Participation in another trial

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):	10-08-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	SuperSeton
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	27-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2017
Application type:	Amendment
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	NL56590.018.16