Prevention of incisional hernias with prophylactic synthetic mesh placement during stoma reversal

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The aim of this study is therefore to prospectively investigate whether prophylactic synthetic mesh placement reduces the rate of stomal site incisional hernias after stoma closure without increasing (infectious) complications.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON47547

Source
ToetsingOnline

Brief title
Prevention of incisional hernias following stoma closure

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym
hernia cicatricalis, incisional hernia

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Voor dit onderzoek is geen financiering nodig;dus niet van toepassing

Intervention

Keyword: hernia cicatricalis, incisional hernia, stoma reversal, synthetic mesh

Outcome measures

Primary outcome

Incisional hernia rate as detected by abdominal ultrasound at 1 year following stoma closure. An incisional hernia was defined as an opening or defect in the abdominal wall with protruding tissue trough it at the stomal incision site.

Secondary outcome

- Clinical diagnosis of incisional hernia at 1 year follow-up

- Number of patients requiring surgical intervention for correction of a incisional hernia

- Postoperative pain

- 30-day mortality, cause of death

- 30-day morbidity, specifically focussing on infectious complications.

- 30-day re-admission and re-operation rate

- Quality of life

- Cost-effectiveness

Study description

Background summary

A recent meta-analyses showed that one in three patients develops an incisional hernia following stoma closure. In addition, approximately fifty percent of these patients require surgical correction. It is important to realize that incisional hernias are a major cause of patient morbidity as they cause abdominal pain, discomfort, impaired quality of life and an increase hospital stay and the number of surgical interventions. According to recent

retrospective comparative studies, prophylactic mesh placement during stoma closure could markedly decrease incisional hernia rate. However, the currently available studies comparing standard stoma closure and mesh-reinforced stoma closure mainly focused on ileostomy closure, included only a limited number of patients and were all retrospective, therefore; strong evidence is lacking.

Study objective

The aim of this study is therefore to prospectively investigate whether prophylactic synthetic mesh placement reduces the rate of stomal site incisional hernias after stoma closure without increasing (infectious) complications.

Study design

Randomized controlled trial, single-blinded.

Intervention

One group (standard arm) receives standard stoma closure and the other group (intervention arm) will have a preventive synthetic mesh placed in addition to standard stoma closure

Study burden and risks

Half of the patients included in the study (intervention arm) will have a synthetic mesh placed in order to prevent incisional hernia development. These meshes have been used in hernia repair for several decades and are regarded as safe. However, in our study, the meshes are placed in possibly contaminated area. Even though several studies have shown that synthetic mesh placement in a mildly contaminated area can be safely performed when using the right surgical techniques, this could in theory still lead to a slightly increased risk of surgical site infection. In order to minimalize this risk several preventive measures will be taken, such as per-operative administration of antibiotics, avoidance of contact between incision site and mesh when placing it in the abdomen and closure of the fascia with PDS (monofilament). In addition, the patients will be asked to fill out quality of life questionnaires five times, which will take approximately 20 minutes.
A possible advantage of participation for patients in the intervention arm could be a lower incidence of incisional hernias. Hereby, patients could be spared from the discomfort and other symptoms associated with incisional hernias. In addition, fewer patients will have to undergo an additional surgical intervention in order to repair an incisional hernia.

Contacts

Public
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ
NL
Scientific
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >18 years
Signed informed consent

Exclusion criteria

Not able to sign informed consent
Connective tissue disorder
Intraperitoneal dialysis
Immunodeficiency
Use of immunosupressive medication (including high dose corticosteroids)
Previous intraperitoneal mesh placement <3cm of the stoma closure wound

allergy of contra-indication for mesh placement
Pregnancy or pregnancy wish in the future
Inflammatory bowel disease as indication for stoma construction

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-07-2018
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Synthetic mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-08-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	19-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 27268
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58088.100.16
OMON	NL-OMON27268