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

No registrations found.

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

Summary

ID

NL-OMON27268

Source
Nationaal Trial Register

Brief title
PRINCE

Health condition

Stoma, incisional hernia.

Sponsors and support

Primary sponsor: No sponsoring
Source(s) of monetary or material Support: No sponsoring

Intervention

Outcome measures

Primary outcome

Incisional hernia at stoma closure site at 1-year follow up, as seen on CT or abdominal ultrasound.

Secondary outcome

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

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

- 30-day morbidity

- 30-day mortality

- 30-day readmission and re-operation rate

- QoL (SF-36, EQ5-D)

- Hernia related Quality of life (HerQLes)

- Cost effectiveness (iPCQ, iMCQ)

Study description

Background summary

Rationale:

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.

Objective:

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

Study design:

Multicentre randomized controlled trial, single-blinded.

Study population:

All patients that undergo stoma closure at Meander Medical Center and Jeroen Bosch Hospital.

Intervention (if applicable):

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.

Main study parameters/endpoints:

Incisional hernia rate as detected by CT or abdominal ultrasound 1 year following stoma closure

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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. This could, in theory, lead to a slight increase in surgical site infection risk. 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 suture).

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.

Study objective

Prophylactic synthetic mesh placement during stoma reversal reduces the rate of stomal site incisional hernias without increasing (infectious) complication rate.

Study design

- Incisional hernia, both clinically and radiologically will be registered at 12 months.

- Questionnaires will be filled in at 0, 3, 6, 9, and 12 months.

- Morbidity, mortality, read-mission and re-operation rate will be registered at 30-days

Intervention

Control group: standard stoma closure

- Closure of fascia

- Peroperative AB prophylaxis (1 dose)

Intervention group: stoma closure + placement of an prophylactic synthetic mesh

- Closure of posterior fascia

- Placement of synthetic mesh

- Closure of anterior fascia

- Skin closure using purse string technique

- Per-operative AB prophylaxis (3 doses)

Contacts

Public
Meander Medical Centre
Thijs Burghgraef

033-8501797
Scientific
Meander Medical Centre
Thijs Burghgraef

033-8501797

Eligibility criteria

Inclusion criteria

- > 18 years

- Indication for colostomy or ileostomy reversal

Exclusion criteria

- Intraperitoneal dialysis

- Connective tissue disease

- Immunodeficiency disease

- Use of immunosuppresive medication

- Allergy/contra-indication for mesh

- Previous intraperitoneal mesh placement < 3 cm of stoma closure wound.

- Pregnancy

- Inflammatory bowel disease as indication for stoma construction

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018

Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-01-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47547
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7460
NTR-old	NTR7702
CCMO	NL58088.100.16
OMON	NL-OMON47547

Study results