PROphylactic Mesh to prevent Incisional hernias at the former Stoma Site: the PROMISS-trial

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To evaluate the incidence of incisional hernias after stoma reversal after preventive mesh placement compared to no mesh placement. Secondly the incidence of parastomal hernias will be recorded and complications caused by preventive mesh placement...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46765

Source
ToetsingOnline

Brief title
The PROMISS-trial

Condition

- Other condition
- Soft tissue therapeutic procedures

Synonym
Incisional hernia at the former stoma site.

Health condition

Aandoeningen van de buikwand

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Incisional hernia, Mesh, Prevention, Stoma

Outcome measures

Primary outcome

The primary goal of this study is to investigate if the incidence of incisional

hernias at the former stoma site is reduced by preventive mesh placement.

Secondary outcome

- Occurrence of parastomal hernia

- Occurrence of stoma prolapse

- Occurrence of mesh infection

- Occurrence of wound infections

- Occurrence of seroma

- Quality of life score

- Operation length

- Time to stoma reversal

- Cost-effectiveness

Study description

Background summary

Approximately 7000 stomata are created in the Netherlands every year. The occurrence of a parastomal herniation is high, with a reported incidence of 4-48%. Also, the former stoma site, after stoma reversal has taken place, is at

increased risk for the development of an incisional hernia. A clinical incisional hernia rate of 30% is reported after stoma reversal. Herniation can cause pain, deformity and possibly incarceration, which results in a significant impact the quality of life of the patient.
The hypothesis of this study is that the use of a prophylactic mesh at the time of stoma formation leads to a lower incidence of incisional hernias after stoma reversal, an improved quality of life and therefore a possible cost reduction in healthcare.

Study objective

To evaluate the incidence of incisional hernias after stoma reversal after preventive mesh placement compared to no mesh placement. Secondly the incidence of parastomal hernias will be recorded and complications caused by preventive mesh placement will be evaluated. In addition, we aim to assess the effect of preventive mesh placement on quality of life and healthcare cost reduction by avoiding re-intervention.

Study design

A multicentre double blind randomized controlled trial with a total follow up of 24 months.
The study will be conducted in the Maastricht University Medical Centre, Rijnstate Ziekenhuis, Elkerliek Ziekenhuis, Canisius-Wilhelmina Ziekenhuis and Zuyderland Medisch Centrum. The operations will be performed by experienced surgeons.
The regular follow-up for colorectal carcinoma will be used for data gathering and CT-scans made during this period will be evaluated for the primary outcome.

Intervention

A preventive mesh will be placed using a sublay keyhole technique (pre-peritoneal, retromuscular) at stoma formation. The mesh (versatex mesh 15x15cm) will be left in situ after stoma reversal and the hole in the mesh will be closed, to prevent incisional herniation. The bowel resection or stoma formation will be performed as planned and is not further altered by the intervention procedure.

Study burden and risks

The standard surgical procedure for the treatment of parastomal hernias is used in a prophylactic fashion. As this is standard care in parastomal hernias the risks are minimal. The mesh that is used is CE approved. The burden of participation in this study is minimal for the patient all follow-up visits coincide with the regular visits for colorectal cancer. Hence, no extra outpatient department visits, and even no additional diagnostics nor other

medical procedures that could potentially burden the patient, are required.

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

- Age * 18 years
- Diagnosed with colorectal carcinoma
- Bowel resection following stoma formation, intended to be temporary.
- Elective surgery
- ASA-score I-III
- Signed informed consent

Exclusion criteria

- Emergency operation
- Peritonitis (i.e. bowel perforation)
- Bowel obstruction
- A life expectancy of less than 2 years (distant metastasis i.e. located in the liver, peritoneum, lung, cerebral or bone)
- Earlier hernia repair with mesh placed in a 10cm proximity of the future stoma site.
- Chronic use of antibiotics
- Chronic use of immunosuppressive medication
- ASA-score IV or above
- Not able to sign informed consent
- Patient being unable to speak Dutch
- Patient allergic to one of the components of the mesh

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	130
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	27-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL63259.068.17