Prevention of Parastomal Hernias and Incisional Hernias in Old Stoma Wounds: a pilot Study

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

Summary

ID

NL-OMON35152

Source
ToetsingOnline

Brief title
Hernia Prevention in Stomas: pilot study

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym
abdominal hernia, incisional hernia, ventral hernia

Research involving
Human

Sponsors and support

Primary sponsor: Algemene Heelkunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: incisional hernia, parastomal hernia, prophylactic mesh

Outcome measures

Primary outcome

The primary objective of this study is postoperative complications after prophylactic mesh placement around a stoma (i.e. infection of the mesh and adhesions to the mesh).

Secondary outcome

Optimizing operative procedures (size of mesh, size of opening in mesh, fixation)

Postoperative complications (anastomotic dehiscence, fistula)

Stoma complications (stenosis, bulging, prolapse, retraction, skin problems)

Wound infection after stoma reversal

Parastomal hernia incidence and incisional hernia incidence after stoma reversal

Quality of Life and Pain score before and after stoma creation with mesh placement and after stoma reversal

Study description

Background summary

Parastomal hernias and incisional hernias in old stoma wounds develop frequently (30-50%) and carry along a significant burden of disease. The idea of a prophylactic mesh has been tested in a Swedish randomized controlled trial (RCT) with the mesh placed upon end colostomy formation. Results suggest this procedure is the panacea against stoma associated herniations. To our knowledge however, the technique is not being applied yet in our or other centres, probably because we still have unanswered questions about the size and ideal position of the mesh, possible complications (infection, adhesions) and the

benefit in terms of quality of life.

Study objective

We would like to conduct a RCT to confirm the hernia prevention effect of a mesh, however in a slightly different position, with a different mesh and with all types of stomas. In addition, we want to measure the possible benefit in terms of quality of life. However, before setting up this RCT we first want to conduct a pilot study of 10 patients to determine the safety (i.e. infection, adhesions) of mesh placement and fine-tune logistics and the operative procedure.

Study design

Pilot intervention study.

Intervention

Placing an intraperitoneal mesh around the stoma at stoma creation.

Study burden and risks

Knowing that the risk of herniation (parastomal or incisional) is 30-50% and the associated morbidity significant, standard placement of a prophylactic mesh might improve the quality of life of a large group of patients. This study is meant to be a pilot study to see whether the mesh related risks of infection and adhesion morbidity are acceptable. To minimize the risk of infection, only patients without any immunocompromise will participate. This study will also identify the ideal surgical technique and assess problems and/or impracticalities of the protocol for the future RCT.
Patients will furthermore undergo their standard treatment with the addition of a mesh placed upon stoma formation. The burden for the patients will be answering the quality of life questions. Since most patients will be oncological patients the number of outpatient follow-up visits will only be incremented by one.
When we compare the potential benefit of a large group of patients receiving this intervention with the potential detrimental effects, we find the former outweighing the latter.

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

- life expectancy at least 1 year
- temporary stoma
- elective surgery
- clean-contaminated abdomen (GI-tract opened)

Exclusion criteria

- ASA score IV or above
- Incapacitated adult or no signed informed consent
- Emergency procedure
- Contaminated or infected* abdomen
- Residual intraperitoneal mesh
- Already injured part of the abdominal wall where the stoma will be sited
- Contraindication to laparoscopy
- Longterm use of corticosteroids and other immunosuppressive agents
- Current antibiotic therapy
- Currently receiving or recently received chemotherapy

- Immune deficiency, ascites, peritoneal dialysis, pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2010
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	26-04-2010
Application type:	Amendment
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
ClinicalTrials.gov	NCT00907842
CCMO	NL27625.068.09