Prevent Trial;Prevention of parastomal hernia during construction of a colostomy by reinforcing the bowel wall with a polypropylene mesh. ;A multicentre randomized controlled trial.

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Patients in whom a permanent (end) colostomy is created in (semi) elective setting are randomised between the placement of a polypropylene mesh during stoma creation and the classic method without a mesh. Primary aim: Does the use of a lightweight...

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

Summary

ID

NL-OMON32175

Source
ToetsingOnline

Brief title
Prevent Trial

Condition

- Abdominal hernias and other abdominal wall conditions
- Gastrointestinal therapeutic procedures

Synonym
hernia next to the stoma

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Tyco Health Care,zon mw subsidie is aangevraagd

Intervention

Keyword: Colostomy, Parastomal hernia, Polypropylene mesh, Prevention

Outcome measures

Primary outcome

Patientcaracteristics including medical history, immunosuppressive diseases and indication for surgery will be documented. (see addendum A for CRF) The preoperative quality of life will be registered using the SF-36 questionsform.

Peroperative technical data of the colostomy and potential riskfactors for complications will be documented.

Postoperatively the presence of infection will be registered according to the Centers of disease control (CDC) criteria. These are the standard criteria in the USA and the Netherlands and are part of the follow-up data forms.

Patientscomplaints regarding the stoma will be registered. This will be done by using the SF-36 and painscore according to Korff. (see addendum B)

Physical exam will be performed to register the potential presence of a parastomal hernia. The stoma dressing has to be removed!

Definition of a parastomal hernia: a swelling next to the stoma during valsalva in upright or flat position.

When there are complaint or suspision of a parastomale hernia an MRI scan is performed unless for other reasons a CT-scan is performed. The treatment of a potential parastomal hernia will be according to the regular standards.

Secondary outcome

The costs will be calculated by comparing the additional costs of the mesh placement with the therapeutic costs of a surgical procedure of a parastomal hernia including the time off work.

Study description

Background summary

A parastomal hernia is a hernia cicatricalis at a stoma site. The incidence varies between 5-50% depending on type of the stoma and follow up methods. Many surgical techniques have been tried to reduce the incidence of a parastomal hernia. Of which the stoma type (ileostomy) and the stoma site (through the rectus muscle) made an improvement, none the less the problem occurs frequently.
The treatment of a parastomal hernia is a difficult problem. Various surgical techniques have been described but the recurrence rate remains considerable (16-40%). For this reason it seems promising to focus on the possible prevention of a parastomal hernia in stead of treatment when one occurs.
There is one randomised, unfortunately prematurely stopped trial of Israelsson, which demonstrates the usefulness of a preventive polypropylene mesh (Vypro, Lightweigth multi&monofilament mesh, Ethicon) in the prevention of a parastomal hernia.
Up until now the use of preventive mesh placement during the creation of a colostomy is not standard practice in the Netherlands. This clears the way for a prospective trial with using a mesh which has proven itself in the treatment of hernias but now to prevent parastomal hernias.

Study objective

Patients in whom a permanent (end) colostomy is created in (semi) elective setting are randomised between the placement of a polypropylene mesh during stoma creation and the classic method without a mesh.
Primary aim: Does the use of a lightweight monofilament polypropylene mesh prevent the occurrence of a parastomal hernia? Asuming an reduction in incidence from 30% in the classic group til 10% in the mesh arm. What are the risks caused by using this mesh for this indication?
Secondary aim: Outway the costs and potential complicaties of a prophylactic lightweigt polypropylene mesh the cost of treatment of a symptomatic parastomal hernia? A cost effectiveness analysis.
What is the influence of a stoma and a possible parastomal hernia on the quality of life and painscores?

Study design

The study is a prospective singleblind (patient) randomised multicentre trial. The patients are eligible after applying the in- and exclusion criteria which will be displayed in the next chapter. The eligible patients will be asked to participate in the trial and will be informed about the pro and con*s of the study before they are asked to sign the informed consent form.
When a patients agrees to participate in the trial he/she will be randomised between the creation of a colostomy with or without the placement of a mesh (ultrapro).
Postoperatively the short and long term complications will be documented together with the painsscores and quality of life (SF-36).

Intervention

To reduce the chance of complications caused by the preventive mesh placement a lightweight partially absorbable monofilament mesh is chosen, Ultrapro (Ethicon, 70 euro). The structure of the mesh allows cutting without losing its integrity. The chance of an infection and fistulation is probably even smaller in these types of mesh compared to a traditional mesh. This mesh is currenty used to correct various types of abdominal wall hernia.

Study burden and risks

After the operation routine follow up will be performed based on the initial diagnosis. This can be combined with follow up for this trial which is scheduled at 1, 2 and 5 years after surgery. This follow up is aimed at the stoma site and each time the patient will be asked to fill in a questionnaire about quality of life and a pain score. If complications occur during (routine) follow-up they will be treated as always.

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

Inclusioncriteria:
1. The creation of a presumed permanent colostomy, in a (semi) elective setting.
2. Age >18 years and <80 years.
3. Informed consent

Exclusion criteria

Exclusioncriteria:
1. A survival shorter than 12 months is expected or metastatic disease is present.
2. Correction of a previous created colostomy, unless a new one is created.
3. A *fresh* bowel wall at the stoma site is not present.

4. An important language barier.
5. Hinchey 4 (generalised faecal peritonitis) is expected.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 22656
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL22695.091.08
OMON	NL-OMON22656