Prevention of a hernia next to a stoma with a prosthetic mesh.

No registrations found.

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

Summary

ID

NL-OMON22656

Source
Nationaal Trial Register

Brief title
Prevent trial

Health condition

Parastomal hernia
polyproylene mesh
surgery
colostomy

Sponsors and support

Primary sponsor: ZonMw
Wetenschapsfonds Heelkunde CWZ
Source(s) of monetary or material Support: ZonMw
Wetenschapsfonds Heelkunde CWZ
Covidien

Intervention

Outcome measures

Primary outcome

The incidence of parastomal hernia.

Secondary outcome

Cost effectiveness analysis, quality of life and pain scores.

Study description

Background summary

Prevention of parastomal hernia with a prosthetic mesh, a multicenter randomized controlled trial.

Aim: Does the use of a monofilament polypropylene mesh in a sublay position during the creation of a colostomy reduce the incidence of parastomale hernia?

Introduction: Treatment of a parastomal hernia remains a difficult problem. One trial (54 patients) demonstrated a beneficial effect of prophylactic placement of a mesh during the formation of a colostomy. But in this trial the follow-up was relatively short and it was prematurely stopped. Until now
the use of a prophylactic mesh is not a standard treatment (in the Netherlands).

Methods: Prospective randomised (single blind) multicentre trial.

Population: Patients with an elective suspected permanent colostomy between the age of 18 and 80 will be asked
to participate unless there is a life expectancy of less than 12 months.

Intervention: A lightweight partially absorbable monofilament polypropylene mesh placed in a sublay
positions as described by Israelsson is compared with a colostomy without a mesh.

Endpoint: The incidence of parastomal hernia with a follow-up after 3 weeks, 3 months, 1, 2 and 5 years.
Secondary
endpoints: cost effectiveness analysis, quality of life and pain scores.

Sample size: A reduction from 30% (non mesh) towards 10% (mesh group) parastomale hernia is expected.
Based on a p-value of 0.05 (alfa), a power of 90% (beta) and a two-sided test 134 patients areneeded. A total of 150 patients will be included with 75 patients in each trial arm
Inclusion time: 11 academic and training hospitals will participate in the inclusion. The inclusion should
be completed after 18 months. The first data analysis and first report will be after one year

follow-up as
generally accepted in hernia research but follow-up will be completed after five years.

Study objective

A lightweight monofilament polypropylene mesh in a sublay position reduces the incidence of a parastomal hernia.

Study design

3 weeks, 3 months, 1 year, 2 years and 5 years.

Intervention

A lightweight monofilament polypropylene mesh placed in a sublay position is compared with formation of an end-colostomy without a mesh.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aanleg van een nieuw electief, in opzet definitief, eindstandig colostoma;

2. >18 jaar en <80 jaar;

3. Informed consent is verkregen.

Exclusion criteria

1. Overleving korter dan 12 maanden is te verwachten of gemetastaseerde ziekte;

2. Correctie van een eerder aangelegd stoma, tenzij een nieuwe wordt gecreëerd;

3. Geen “maagdelijke buikwand” op de stoma plaats;

4. Belangrijke taalbarrière.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion
Date: 18-09-2009
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32175
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1902
NTR-old	NTR2018
CCMO	NL22695.091.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32175

Study results

Summary results
N/A