ISRCTN95093825 https://doi.org/10.1186/ISRCTN95093825

Prophylactic mesh in urostomies does it help to prevent stoma hernia?

Submission date	Recruitment status	[_] Prospectively registered
22/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2020	Digestive System	

Plain English summary of protocol

Background and study aims
Removal of the bladder (called cystectomy) is sometimes necessary, for example when serious forms of bladder cancer are diagnosed. After a bladder removal, the urine must be collected somehow. The most common way to do that is via a urostomy, when a section of the small intestine is drawn through the abdominal wall and a plastic bag is placed at the end on the skin in order to collect urine. A urostomy may cause a hernia and a 50% risk has been seen in some studies. Abdominal content (fat or small intestine) will bulge out and make the attachment of the plastic bag difficult. A hernia can also cause pain, discomfort or bowel obstruction (called ileus) and an operation will be needed. One way to prevent the formation of a hernia is to put a mesh (a plastic net) around the urostomy. The aim of the study is to assess whether using such a mesh will reduce the number of hernias.

Who can participate?
All patients undergoing cystectomy who are above 18 and have not had a stoma (opening of the abdomen) or hernia before.

What does the study involve?
Half of them will be operated the new way, with a mesh and the other half will be operated the old way, without. All patients above the age of 18 and not having a stoma or hernia before, can participate. We will check the patients with clinical examination and computed tomography (CT) 3, 6, 12 and 24 months after operation and look for hernias, complications of the mesh and evaluate how easy it is to bandage the urostomy. We want to include 200 patients in the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is led from Helsingborg (Sweden) and there are three sites.

When is the study starting and how long is it expected to run for?
The study started in May 2012 and the aim is to include 200 patients by 2015. The final results are expected to be published in 2017-2018.

Who is funding the study?
Stig and Ragna Gorthon Foundation and Thelma Zoega Foundation (Sweden).

Who is the main contact?
Dr Petter Kollberg
petter.kollberg@skane.se

Contact information

Type(s)
Scientific

Contact name
Dr Mats Blackberg

Contact details
Sodra Vallgatan 5
Helsingborg
Sweden
25437
-
mats.blackberg@skane.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prophylactic mest at Bricker urostmy - a prospective randomized multicenter trial regarding stoma hernia with or without mesh

Study objectives
Parastomal mesh lower the frequency of parastomal hernias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Etikprövningsnämnden aprroval on 22/05/2012, reference 2012/236

Study design
Prospective randomized multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Abdominal wall hernia

Interventions
Application of a retromuscular parastomal composite net versus no net.

We randomize patients to either have a stoma mesh or not. The mesh is applied around the stoma, in the abdominal wall behind the rectus muscle. Those operated without a mesh are operated using the standard procedure.

All participants will be followed for 24 months and undergo at computerized tomography (CT) at 6, 12 and 24 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of parastomal hernia at 6, 12 and 24 months postoperatively

Secondary outcome measures
1. Infection frequency at 30 days postoperatively
2. Net related complications during 24 months postoperatively
3. Cost of stomal bandaging 24 months postoperatively

Overall study start date
01/06/2012

Completion date

31/12/2015

Eligibility

Key inclusion criteria
1. Patient planned for cystectomy with Bricker conductor
2. Patient age above age of 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
242

Key exclusion criteria
1. History of former abdominal stoma
2. Present abdominal stoma
3. Former or present abdominal wall hernia

Date of first enrolment
01/06/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Sodra Vallgatan 5
Helsingborg
Sweden
25437

Sponsor information

Organisation
Thelma Zoega Foundation (Sweden)

Sponsor details
Box 117
Lund
Sweden
22100
-
matilda.wadenbaeck@eken.lu.se

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Stig and Ragna Gorthon Foundation (Sweden) No 86485

Funder Name
Thelma Zoega Foundation (Sweden) No 86476

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	19/08/2020	Yes	No