

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

Submission date 22/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/08/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Prophylactic mest at Bricker urostomy - 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 approval on 22/05/2012, reference 2012/236

Study design
Prospective randomized multicenter trial

Primary study design
Interventional

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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