Bard® PolySoft* pre peritoneal mesh versus Parietene* ProGrip* self-fixing semi-resorbable mesh and chronic inguinal pain development.

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Objective of the Trial:Does the use of a Bard® Polysoft* preperitoneal mesh result in less chronic pain than after the use of a ProGrip*self-fixing semi-resorbable mesh for patients with an inguinal hernia repair through an anterior approach?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35542

Source
ToetsingOnline

Brief title
SoftGrip Trial

Condition

- Therapeutic procedures and supportive care NEC

Synonym
groin hernia, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic pain, inguinal hernia, mesh

Outcome measures

Primary outcome

Objectives:

Primary:

- Alternation in the painscore on the Visual Analog Scale and the 0-6 point

Verbal Descriptor Scale.

Secondary outcome

Objectives:

Secundary:

- Occurrence of hernia inguinalis recurrence objectified by physical

examination and/or ultrasound.

- Complications; for example recurring haemorrhage and infections

- Alternation in the quality of life measured by the SF-36 questionaire.

Study description

Background summary

Background:
With the introduction of prosthesis material, the Lichtenstein technique has reduced the recurrence rate after inguinal hernia surgery to an acceptable level (2%). Polypropylene mesh is the first choice prosthesis material in most Dutch hospitals.
However, chronic pain after inguinal hernia surgery remains a problem. A number of studies demonstrated that 20 - 40% of patients experience chronic pain after elective inguinal hernia surgery1-8. This is due to the occurrence of extensive

fibrosis that is induced by a standard polypropylene mesh, although the method of fixation, with non-resolvable stitches, might also play a role in the pathogenesis of chronic pain.
Therefore two new types of mesh prostheses have been developed to prevent the occurrence of chronic pain. The first type is self-adhesive and light-weight, the second is self-fixing and has the advantage of a preperitoneal correction through an open anterior approach.
In theory this could possibly prevent chronic pain on both pathogenesis pathways.
Both the extent of fibrosis, as the chance of nerve-incarcaration and/or periostitis through incorrectly placed sutures, could be reduced.

Study objective

Objective of the Trial:
Does the use of a Bard® Polysoft* preperitoneal mesh result in less chronic pain than after the use of a ProGrip*self-fixing semi-resorbable mesh for patients with an inguinal hernia repair through an anterior approach?

Study design

Trial Design:
This study is a double blind randomized controlled trial in patients with a unilateral primary inguinal hernia. A total of 258 patients will be included into the entire study and randomized into either ARM A, the control group, ProGrip* mesh (129 patients), or ARM B, Bard® Polysoft* mesh (129 patients). The Bard® Polysoft* mesh will be placed preperitoneal, whilst the ProGrip mesh will be placed according to the Lichtenstein technique. In both groups correction will be performed through an anterior approach.

Study burden and risks

Hypothesis:
Compared to a ProGrip self-fixing semi-resorbable mesh the use of a Bard® Polysoft* preperitoneal mesh results in less chronic groin pain in inguinal herniorrhaphy patients.

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

1. Age of 18 years or older
2. An unilateral primary inguinal hernia.
3. Adequate follow-up possible

Exclusion criteria

1. Incarcerated inguinal hernia
2. Recurrent inguinal hernia
3. Local inguinal inflammation
4. Concurrent femoral hernia
5. ASA 4 or more
6. Adequate follow-up impossible
7. Previous inguinal surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2010
Enrollment:	258
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2010
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL24683.041.09