The effect of two anterior approaches to inguinal hernia repair, pre peritoneal Bard® Polysoft™ self expanding patch versus a ProGrip self-fixing semi-resorbable mesh, on the development of acute and chronic inguinal pain.

Gepubliceerd: 25-08-2009 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24826

Bron
NTR

Verkorte titel
SoftGrip Trial

Aandoening

Inguinal hernia, chronic pain, mesh

Ondersteuning

Primaire sponsor: Ziekenhuis Gelderse Vallei, Department of General Surgery
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Does the use of Bard® Polysoft™ preperitoneal mesh result in less chronic groin pain than the use of the ProGrip™ self-fixing semi-resorbable mesh in inguinal herniorrhaphy patients?

Toelichting onderzoek

Achtergrond van het onderzoek

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 surgery. 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-incarceration and/or periostitis through incorrectly placed sutures, could be reduced.

Objective of the Trial:

Primary: 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?

Secondary:

1. Does the use of Bard® Polysoft™ mesh result in a different recurrence rate than the use of a ProGrip™ mesh?

2. Does the use of a Bard® Polysoft™ mesh attend with less peri- and early postoperative complications than the use of a ProGrip™ mesh?

3. Does the use of a Bard® Polysoft™ mesh result in a faster resumption of work than the use of a ProGrip™ mesh?

4. Does the use of a Bard® Polysoft™ mesh result in a higher quality of life than the use of a ProGrip™ mesh.

Trial Design:

This study is a double blind randomized controlled trial in patients with a unilateral primary inguinal hernia. A total of 460 patients will be included into the entire study and randomized into either ARM A, the control group, ProGrip™ mesh (230 patients). or ARM B, Bard® Polysoft™ mesh (230 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.

Follow-up:

Patients will be followed-up for at least one year. At 2, 12 weeks and 12 months the following factors will be registrated: pain, inguinal hernia recurrence, occurrence of complications, quality of life and work resume.

Doel van het onderzoek

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.

Onderzoeksopzet

1. 2 weeks;

2. 12 weeks;

3. 12 months;

4. Possibly 5 years.

Onderzoeksproduct en/of interventie

Inguinal herniorrhaphy by using the ProGrip™ self-fixing semi-resorbable mesh (group A) or the Bard® Polysoft™ preperitoneal mesh (group B).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age of 18 years or older;

2. A unilateral primary inguinal hernia;

3. Adequate follow-up possible.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2009
Aantal proefpersonen:	460
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1853
NTR-old	NTR1965
Ander register	METC number : 09-162
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A