A double-blind randomized controlled trial comparing PArietene self-fixing semi-Resorbable mesh with standard heavy-weight polypropylene mesh on chronic inguinal pAin DEvelopment

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Primary:Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in less chronic inguinal pain as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31651

Source
ToetsingOnline

Brief title
PARADE trial

Condition

- Soft tissue therapeutic procedures

Synonym
Chronic pain after inguinal hernia repair

Research involving
Human

Sponsors and support

Primary sponsor: Tyco Health Care
Source(s) of monetary or material Support: Covidien (voorheen Tyco health care)

Intervention

Keyword: Chronic pain, Inguinal hernia, Lightweight mesh

Outcome measures

Primary outcome

Pain assessment (6-point Verbal Rating Scale and Surgical Pain Scales)

Secondary outcome

Recurring inguinal hernia (physical examination/ ultrasonography), peri- and

early postoperative complications (questionnaire), return to daily actvities

(questionnaire), quality of life (SF-36)

Study description

Background summary

Recurrence rates in inguinal surgery have been drastically reduced with the introduction of prosthetic materials. However, with incidence rates ranging from 20 to 40% chronic postherniorrhaphy inguinodynia remains a worrisome complication. Careful analysis has identified neuropathic pain caused by damaged and entrapped nerves as a major contributor. Both surgical technique as implanted materials could be withheld responsible. Although, the induced fibrotic response creates a proper hernioplasty, it can result in a painful nerve entrapment as well. Another possible pain initiator can be found in suturing the mesh, since nerve tissue and periostal layers of the pubic bone may be grapped along with other tissues. To prevent such painful sequelae a new type of mesh has been developed which exhibits both semi-resorbable and self-fixing properties. Less fibrotic tissue reaction combined with sutureless implantation may result in less chronic pain following inguinal hernia repair.

Study objective

Primary:

Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in less chronic inguinal pain as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the Lichtenstein technique?

Secondary:
1. Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in a different recurrence rate as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the Lichtenstein technique.?
2. Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in less peri- and early postoperative complicaties as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the Lichtenstein technique?
3. Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in an earlier return to daily activities as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the Lichtenstein technique?
4. Does the implementation of a Parietene® self-fixing semi-resorbable mesh (Covidien-Sofradim) result in a better quality of life as compared to a standard polypropylene mesh (Marlex®; Bard) in the treatment of a inguinal hernia using the Lichtenstein technique?

Study design

Monocentric double-blind randomized controlled trial
(Máxima Medical Centre, Eindhoven/ Veldhoven The Netherlands)

Intervention

In the studygroup the Parietene lightweight self-fixing mesh (Tyco-Sofradim) is used. In the controlgroup a standard polypropylene mesh is used. both groups are treated according to the Lichtenstein technique.

Study burden and risks

There are no known side-effects of the Parietene® self-fixing semi-resorbable mesh. In theory, the lightweight en self-fixing qualities of the mesh may result in a higher recurrence rate. Possible short-term complications of the inguinal hernia repair itself, are bleeding, seroma formation and wound infecton.

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. Primary unilateral inguinal hernia
2. Age: * 18 years old

Exclusion criteria

1. Signs of incarceration
2. Signs of local infection
3. Presence of chronic inguinal pain following a previous vasectomy, Pfannenstiel incision, appendectomy
4. ASA IV
5. Adequate follow up not possible: mental retardation, dementia, foreign language, living in

asylum seekers centre

Study design

Design

Study type:	Interventional
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):	01-04-2008
Enrollment:	350
Type:	Actual

Medical products/devices used

Generic name:	Parietene® self-fixing semi-resorbable inguinal hernia mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-03-2008
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL21180.015.07