Randomised controled trial comparing the effect of a new self-gripping semi-resorbable Parietene Progrip mesh and the sutured Polypropylene mesh on the incidence of chronic inguinodynia in Lichtenstein hernioplasty.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33251

Source
ToetsingOnline

Brief title
Inguinodynia after Lichtenstein: Polypropylene versus Parietene Progrip

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
groin hernia, hernia inguinalis

Research involving

Human

Sponsors and support

Primary sponsor: Groene Hart Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic pain, Lichtenstein, mesh, neuralgia

Outcome measures

Primary outcome

1. Amount of post-operative and chronic nociceptive and neuropathic groin pain.

2. Recurrence rate

Secondary outcome

1. Peroperative and post-operative complications like infection, formation of

haematoma or seroma.

2. Operating time

3. Costs

4. Easiness of use

5. Return to work and daily activities

6. quality of life

Study description

Background summary

Surgical repair of groin hernias is one of the most commonly performed operations in the Western world. Use of a prosthetic mesh has become popular since recurrence, acute and chronic post-operative pain rates are significantly lower than in autologous repair. In 1984 Lichtenstein popularized routine use of a polypropylene mesh to create a tension-free hernioplasty, thereby

minimizing postoperative discomfort. This technique has become the gold standard in open tension-free hernioplasties due to its effectiveness, easiness, safety and low rate of complications and recurrences. Furthermore it can be performed under local anaesthesia in a day care setting. However, in the past years different researches showed that patients who had underwent a Lichtenstein hernioplasty suffered high rates of post-operative pain en neuralgia in the groin lasting for months till years. Chronic post-operative pain has been defined as pain lasting more than 3 months after surgery. The estimated occurrence of chronic groin pain is 11% with a range from 0%-63% due to different definitions of pain. More than a quarter of these patients suffers moderate to severe pain, mostly from a neuropathic origin. According to the Committee of the International Association for the Study of Pain nociceptive and neuropathic pain (neuralgia) are initiated or caused by actual or potential damage of tissue respectively nerves or a dysfunction of the latter. This damage can be caused by dissection during operation or unnoticed capture or compression of muscle and nerve fibers by the mesh and the sutures. This will cause muscle ischaemia or even necrosis and entrapment neuropathy. Post-operative, complications like inflammation (periostitis, foreign body reaction to mesh or sutures), wound infection, forrmation of haematoma, granuloma or seroma can cause damage to and neuroma formation of the sensory nerves located in the groinregion: ilioinguinal, iliohypogastric, genitofemoral or lateral femoral cutaneous nerve.
The pain from nerve entrapment or neuroma may arise direct post-operatively or months after surgery. Once developed the pain will not improve over time since neuralgia can exists with no continuous nociceptive input. Patients complain of a burning, numbness or painful sensation in the groin region, testicles, vulva and/or medial side of the upper leg.
For years it has been common practice in Lichtenstein hernia repair to use a heavy weight mesh fixed with non-absorbable sutures; the latter to avoid migration of the mesh which can lead to recurrence of the hernia. However the above makes clear that although the Lichtenstein hernioplasty is a tension-free technique, the use of these sutures and mesh cause a high rate of post-operative pain and neuralgia on the account of a very low recurrence rate. In the past years there has been looked for alternatives to the sutures and heavy weight meshes to avoid these problems. Some advocate to use light weighted meshes. Others recommend reducing the amount of sutures used or implement non-compressive absorbable devices. This is believed to reduce pressure neuropathy and to minimize an inflammatory reaction on the mesh and sutures causing painful adhesives. Other solutions investigated on are the use of glue, routine neurectomie and laparoscopic hernia repair. In this research a semi-resorbable self fixing mesh will be investigated. It is presumed that the semi-resorbable characteristics reduce the amount of foreign body reaction thereby minimizing damage to the surrounding tissue and nerves. The self fixing properties are believed to enhance this effect by minimizing entrapment of muscle and nerve fibres.

Study objective

The aim was to compare the results of a Lichtenstein hernioplasty using a self grippng mesh with the classical Lichtenstein repair using a polypropylene sutured mesh in terms of post-operative and chronic inguinodynia (caused by nerve irritation, neuralgia, painfull fixation sites) and recurrence. The hypothesis is that the semi-resorbable self gripping mesh will result in less chronic inguinodynia in short- and long-term observations without enhancing the amount of recurrences.

Study design

Monocenter dubble blind randomized controlled trial

Intervention

Lichtenstein hernioplasty using a new self grippng Parietene Progrip Mesh (group A) compared to a classic haevy weigth polypropylene mesh (group B).

Study burden and risks

Er zijn geen extra risico's voor de proefpersonen in de onderzoeksgroep. De verwachte afname van post-operatieve pijnklachten ondervangt het meest voorkomend nadeel van de standaard behandeling.

Overzicht van tijdstip en inhoud van follow-up:

Parietene Progrip Studie Vragenlijst Lichamelijk onderzoek
Pre-operatief 1 1
Postoperatief:
2 weken
2
1
3 maanden
2
1
12 maanden
2
1
24 maanden 2 1

1= polikliniek; 2 = thuis
Tijdsduur in minuten: pre-operatief 30min, post-operatief 10min

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. Capacitated male person, age 18 years or older
2. Unilateral inguinal hernia

Exclusion criteria

1. Concurrent femoral hernia
2. Incarcerated inguinal hernia
3. ASA 4 or more
4. Adequate follow up impossible because of mental retardation, dementia, foreign language speaker.

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):	25-07-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL27506.058.09