THE EFFECT OF MESH TYPE (ULTRAPRO VERSUS PROLENE) ON POSTOPERATIVE PAIN AND WELL-BEING FOLLOWING TOTALLY EXTRAPERITONEAL (TEP) LAPAROSCOPIC HERNIA REPAIR: A RANDOMIZED CONTROLLED TRIAL.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38149

Source
ToetsingOnline

Brief title
TULP

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym
groin hernia, inguinal hernia

Health condition

liesbreuken

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Financiering tot op heden door Maatschap Chirurgie (Liesbreukcentrum).

Intervention

Keyword: hernia, mesh type, postoperative pain, quality of life

Outcome measures

Primary outcome

Frequency of chronic pain 3 months after Totally Extraperitoneal (TEP)

endoscopic hernia repair. For the primary study outcome the Definition of the

International Association for the Study of Pain' is used, in which chronic pain

is defined as pain 'still present 3 months after the operation'.

Secondary outcome

Secondary objectives are: Frequency of early postoperative pain (1 week after

surgery), pain at 6 weeks, 1 year, 2 year and 3 year.

Recurrene Rate, Mesh *feeling*, Sensitivity disorders (such as hypo- or

hyperaesthesia), Sexual functioning related to pain, Postoperative

complications (such as wound infection/hematoma/urinary tract

infection/hydrocele etc.), Time to postoperative recovery (return to work and

daily activities), Occurrence of long-term complications (e.g. testicular

atrofia).

Study description

Background summary

Chronic pain following elective inguinal hernia repair is common. Approximately 14%-54% of patients still experience some degreee of inguinal pain several years after succesful surgery (loos 2007).
In recent years, clinical research has focused therefore increasingly on chronic pain and chronic dysesthesias after inguinal hernia repair.
In a review by Mattews et al it is stated that totally extraperitoneal (TEP) endoscopic hernia repair (when performed by an experienced surgeon) has a favorable effect on postoperative pain when compared to conventional (open) hernia repair.
Moreover, recent studies suggest that a lightweight mesh may be associated with less chronic postoperative pain compared to a heavyweight mesh.
A combination of Totally Extraperitoneal (TEP) Endoscopic hernia repair with a lightweight mesh might therefore be the solution in the prevention of postoperative pain.
A randomised controlled trial with long-term follow up in which the two types of meshes (lightweight and heavyweight) are compared is considered to be appropriate.
At the Inguinal Hernia Repair Centre Zeist (In Dutch: Liesbreukcentrum Zeist), approximately 1100 laparoscopic hernia operations are performed every year by experienced surgeons. This makes this Centre a perfect setting for a randomized controlled trial like this.

Study objective

In this trial the outcomes of an Ultrapro mesh after endoscopic hernia repair (TEP) will be compared with the outcomes of a heavyweight mesh (Prolene) after TEP hernia repair. The primary objective is to determine the effect of a lightweight mesh (Ultrapro) compared to a heavyweight (Prolene) mesh on chronic postoperative pain 3 months after totally Extraperitoneal (TEP) endoscopic hernia repair. The purpose is to determine which mesh is the better one in preventing chronic pain.
Chronic postoperative pain is thereby defined as pain at the operation site still existing >= 3 months after surgery.

Study design

Randomized controlled monocentre (specialized centre) trial: the follow-up is 3 years after surgery.

Intervention

Intervention 1: heavyweight mesh (Prolene):
The heavyweight mesh Prolene® is the standard used at a TEP hernia repair in the Hernia Centre Zeist (Dutch: Liesbreukcentrum Zeist). Mesh characteristics are:
Structure: monofilament with small pores
Polymer fiber: Polypropyleen
Weight: 80-85 g/m2

Intervention 2: lightweight mesh (Ultrapro):
50% of participants ('intervention' group) will be randomized to receive this mesh. Mesh characteristics are:
Structure: Multifilament with large pores (3-4 mm)
Polymer fiber: Polypropylene (PP) + Monocryl component (Poliglecapron).
Weight: 28 g/m2 (part of polypropylene which is not absorbed)
The monocryl part (polyglecapron) is absorbed in 90-120 days due to hydrolysis; a lightweight mesh with a pore size of 3-4 mm is what remains.

Study burden and risks

Both meshes (Ultrapro and Prolene) are already being used in endoscopic hernia repair surgery. So we expect that there are no additional risks associated with this trial compared to 'regular' hernia surgery and treatment. Peroperative and perioperative care for patients who participate in this trial is also not different from regular per- and perioperative care.

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

Male patients
>= 18 year old
Primary, unilateral, symptomatic, reducible hernia
Totally Extraperitoneal (TEP) endoscopic hernia repair

Exclusion criteria

Bilateral hernia
Scrotal hernia
Recurrent hernia
Walking distance < 500 m.
Collagen disorders, such as Marfan Syndrome
Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address or insufficient comprehension of Dutch language will be excluded).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	950
Type:	Actual

Medical products/devices used

Generic name:	lightweight mesh (Ultrapro)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-03-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19969

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL30223.100.09
Other	op trialregister.nl: trial ID is NTR2131
OMON	NL-OMON19969