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.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19969

Source
NTR

Brief title
TULP

Health condition

(Endoscopic) hernia repair surgery/ (endoscopische) liesbreukchirurgie

Chronic pain/ Chronische pijnklachten

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht/Zeist
The Netherlands
Source(s) of monetary or material Support: Diakonessenhuis Utrecht/Zeist
The Netherlands

Intervention

Outcome measures

Primary outcome

Frequency of chronic pain after Totally Extraperitoneal (TEP) endoscopic hernia repair.

Secondary outcome

1. Recurrene Rate;

2. Mesh ‘feeling’;

3. Sensitivity disorders (such as hypo- or hyperaesthesia);

4. Sexual functioning related to pain;

5. Postoperative complications (such as wound infection/hematoma/urinary tract infection/hydrocele etc.);

6. Time to postoperative recovery (return to work and daily activities);

7. Occurrence of long-term complications (e.g. testicular atrofia).

Study description

Background summary

In this trial a lightweight mesh (Ultrapro) will be compared with a standard heavyweight mesh (Prolene) on chronic postoperative pain and quality of life after endoscopic inguinal hernia repair.

Study objective

To assess the outcomes of endoscopic hernia repair (TEP) after implantation of a lightweight mesh (Ultrapro) versus a heavyweight mesh (Prolene). The hypothesis is that an endoscopic hernia repair with implantation of a lightweight mesh results in less chronic postoperative pain than endoscopic repair with implantion of a heavyweight (standard Prolene) mesh.

Study design

Screening/Baseline, day 1, 1 week, 6 weeks, 3 months, 1 year, 2 year, 3 year after surgery.

Intervention

Arm 1 (intervention group): lightweight mesh (Ultrapro):
50% of participants will be randomized to receive this mesh.
Mesh characteristics are:

1. Structure: Multifilament with large pores (3-4 mm);

2. Polymer fiber: Polypropylene (PP) + Monocryl component (Poliglecapron);

3. 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.

Arm 2 (Control group): heavyweight mesh (Prolene):
The heavyweight mesh Prolene® is the standard used at a TEP hernia repair in the Hernia Centre Zeist (Dutch: Liesbreukcentrum Zeist). 50% of participants will be randomized to receive this mesh.
Mesh characteristics are:

1. Structure: monofilament with small pores;

2. Polymer fiber: Polypropyleen;

3. Weight: 80-85 g/m2.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male patients;

2. ≥ 18 year old;

3. Primary, unilateral, symptomatic, reducible hernia;

4. Totally Extraperitoneal (TEP) endoscopic hernia repair.

Exclusion criteria

1. Bilateral hernia;

2. Scrotal hernia;

3. Recurrent hernia;

4. Walking distance < 500 m;

5. Collagen disorders, such as Marfan Syndrome;

6. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	950
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38149
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2014
NTR-old	NTR2131
CCMO	NL30223.100.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38149

Study results

Summary results

N/A