

# 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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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 (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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:** Diaconessenhuis 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.

Recurrance 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 degree of inguinal pain several years after successful 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 Matthews 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  $\geq 3$  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/m<sup>2</sup>

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/m<sup>2</sup> (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. Perioperative 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

$\geq 18$  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

6 - THE EFFECT OF MESH TYPE (ULTRAPRO VERSUS PROLENE) ON POSTOPERATIVE PAIN AND WELL ...  
5-06-2025

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