

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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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19969

Bron

Nationaal Trial Register

Verkorte titel

TULP

Aandoening

(Endoscopic) hernia repair surgery/ (endoscopische) liesbreukchirurgie

Chronic pain/ Chronische pijnklachten

Ondersteuning

Primaire sponsor: Diaconessenhuis Utrecht/Zeist
The Netherlands

1 - THE EFFECT OF MESH TYPE (ULTRAPRO VERSUS PROLENE) ON POSTOPERATIVE PAIN AND WELL ...
10-06-2025

Overige ondersteuning: Diakonessenhuis Utrecht/Zeist
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 implantation of a heavyweight (standard Prolene) mesh.

Onderzoekopzet

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

Onderzoeksproduct en/of interventie

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
2 - THE EFFECT OF MESH TYPE (ULTRAPRO VERSUS PROLENE) ON POSTOPERATIVE PAIN AND WELL ...

10-06-2025

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.

Contactpersonen

Publiek

Prof. Lorentzlaan 76
N. Schouten
Zeist 3707 HL
The Netherlands
+31 (0)30 6989214

Wetenschappelijk

Prof. Lorentzlaan 76
N. Schouten
Zeist 3707 HL
The Netherlands
+31 (0)30 6989214

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male patients;

2. ≥ 18 year old;
3. Primary, unilateral, symptomatic, reducible hernia;
4. Totally Extraperitoneal (TEP) endoscopic hernia repair.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	950

Type:

Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:

03-12-2009

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38149

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A