

# TREPP compared to Lichtenstein's technique for inguinal hernia: what's best?

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| <b>Submission date</b><br>19/07/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/07/2016 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>06/11/2018       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

An inguinal hernia is a common condition in which part of the abdominal wall bulges through a weakened abdominal (tummy) wall. To prevent the intestines from becoming trapped, it is necessary to surgically reinforce the abdominal wall. This is usually done using an artificial mesh made from a material called polypropylene. If you compare this to a weakened tire of a bike, it can be imagined that the inner tire bulges out through the weakened outer tyre: the mesh can be sewn on the outer tire (Lichtenstein technique) or it position the mesh in between the inner and outer tire so that the pressure of the inner tire keeps the mesh (without the need for fixation) in position (TREPP method). The aim of this study is to compare the effectiveness of these two techniques and to find out which causes less pain after surgery.

### Who can participate?

Adults without any life-threatening diseases who have an inguinal hernia on one side.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group undergo surgery and have the mesh sewn onto the outside of the abdominal wall (Lichtenstein technique) like an overlay, which is currently standard practice. Those in the second group have the mesh placed on the inside of the abdominal wall (TREPP method). Participants are have their level of pain and general health assessed at the start of the study and then again after 6 weeks, 6 months and 12 months. The cost effectiveness of the two methods is also calculated and compared.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks for those participating in this study compared to any other hernia repair operations taking place outside of the study.

### Where is the study run from?

Medical Center Leeuwarden (Netherlands)

### When is the study starting and how long is it expected to run for?

June 2016 to December 2021

Who is funding the study?

1. The Adriaan Metius Foundation (Netherlands)
2. Surgical Cooperation Friesland (Netherlands)
3. Medical Center Leeuwarden (Netherlands)

Who is the main contact?

Dr Thomas Zwols  
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**Study website**

www.heelkundefriesland.nl

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

V1.2

## Study information

**Scientific Title**

Protocol for a randomised clinical trial comparing the Trans RECTussheath PrePeritoneal repair (TREPP) versus Lichtenstein's technique for inguinal hernia

**Acronym**

TREPPoLi

### **Study objectives**

Inguinal hernia repair according to the TREPP technique results in less patients with chronic postoperative inguinal pain (CPIP) compared to Lichtenstein's technique.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Multi-centre double-blind randomised parallel trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

[www.LiesbreukcentrumNoordNederland.nl](http://www.LiesbreukcentrumNoordNederland.nl)

### **Health condition(s) or problem(s) studied**

Primary unilateral inguinal hernia

### **Interventions**

Following provision of informed consent, participants are randomised to one of two groups.

Group 1: Participants undergo inguinal hernia repair according to the TREPP technique. To reach the preperitoneal space (PPS), a 5 cm transverse incision is made approximately 1 cm cranial to the pubic bone. The anterior rectus sheath is opened by transverse incision. After retraction of the muscle fibers medially, the inferior epigastric vein and artery are identified and retracted medially. The underlying transverse fascia is opened transversely as well. With a gentle movement, the PPS is dissected and a medial hernia may be reduced immediately. Using the iliac vessels as a landmark, the funiculus is identified with the spermatic cord, the testicular vessels and a possible lateral hernia. The latter (if present) may now be reduced. Using three long and thin retractors, a perfect overview of the PPS may be achieved and all possible hernia orifices (medial, lateral and/or femoral) can be visualized. The soft mesh is positioned in the PPS and covers the complete myopectineal orifice of Fruchaud. After deployment, the abdominal pressure keeps the mesh in position, without the necessity of any fixation. The anterior rectus sheath and the fascia of Scarpa are closed with Vicryl.

Group 2: Participants undergo inguinal hernia repair according to Lichtenstein's technique via anterior approach with a skin incision two centimetres above the Poupart ligament. The Lichtenstein technique will be adapted to present-day insights; a soft mesh will be used instead of the 'heavy' polypropylene mesh. The mesh will be positioned as onlay (or 'inlay', as it is, basically, positioned IN the inguinal canal). The skin will be closed the same way as the TREPP technique, using an intracutaneous technique with a resorbable wire.

The surgery will be between 15 and 45 minutes estimated for both techniques (TREPP and Lichtenstein). Preferably spinal anesthesia will be used in both groups (if the patient is choosing general anesthesia this is, of course, provided). A physical exam will be done for every evaluation of numbness of the operation area; questionnaires are filled in (e.g. SF-36, EuroQol 5D, pain disability index) after 6 weeks, 6 months and 1 year.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Chronic postoperative inguinal pain (CPIP) is measured using a visual analogue scale (VAS) in combination with the proposed Quantitative sensory testing (QST) at baseline, 6 weeks, 6 months and 1 year

### **Secondary outcome measures**

1. Health status is measured using the Short Form 36 (SF-36), EuroQol5D (EQ-5D), Carolina comfort scale and Pain Disability index and a physical examination at baseline, 6 weeks, 6 months and 1 year
2. Cost-effectiveness of the interventions is completed by calculating all direct and/or indirect costs (hospital and societal related costs) at 12 months (this means: at the end of the trial, once the last patient fulfilled the final visit)

### **Overall study start date**

01/06/2016

### **Completion date**

31/12/2021

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years and over
2. ASA classification 1-3
3. Symptomatic primary unilateral inguinal hernia

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

356 patients per group, 712 total, rounded up to 750 to make up for lost-to-follow-up

**Key exclusion criteria**

1. Previous preperitoneal operations (e.g. prostatectomy, Caesarean section)
2. Bilateral hernias
2. Recurrent hernias
4. Incarcerated hernias (acute)
5. Inadequate mental state and/or IQ limitations to answer questionnaires
6. Mental disorders (DSM V)

**Date of first enrolment**

01/01/2019

**Date of final enrolment**

31/12/2020

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****Medical Center Leeuwarden**

Medical Center Leeuwarden

Department of Surgery

Henri Dunantweg 2

Leeuwarden

Netherlands

8901 BR

**Sponsor information****Organisation**

Medical Center Leeuwarden

**Sponsor details**

Henri Dunantweg 2

Leeuwarden

Netherlands

8901 BR

**Sponsor type**

Hospital/treatment centre

**Website**

www.MCL.nl

**ROR**

<https://ror.org/0283nw634>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

The Adriaan Metius Foundation

**Funder Name**

Surgical Cooperation Friesland

**Funder Name**

Medical Center Leeuwarden

## **Results and Publications**

**Publication and dissemination plan**

All data (benefit and harm outcomes) will be published in peer reviewed journals, at least indexed in PubMed. The protocol of this trial will be published with all its complete details in the near future, after all the requirements (ethics approval, internal and external audits completed, Good Clinical Practice (GCP) check list points) are obtained.

**Intention to publish date**

01/01/2020

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request