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

Submission date	Recruitment status	[X] Prospectively registered
19/07/2016	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
29/07/2016	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
06/11/2018	Musculoskeletal Diseases	[ ] 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-threathening 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
thomas.zwols@znb.nl

Study website
www.heelkundefriesland.nl

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Zwols

ORCID ID
http://orcid.org/0000-0002-9277-5975

Contact details
Medisch Centrum Leeuwarden
Henri Dunantweg 2
Leeuwarden
Netherlands
8934 AD
+31 (0)58 2863860
Thomas.Zwols@znb.nl

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

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