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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23859

Source
NTR

Brief title
the TREPPoLi trial

Health condition

TREPP reduces the amount of patients with chronic postoperative inguinal pain (CPIP) compared with Lichtenstein's technique.

Sponsors and support

Primary sponsor: Stichting Adriaan Metius
Cooperatie Heelkunde Friesland
Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Adriaan Metius
http://www.adriaanmetiusstichting.nl

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Health status is measured using the Short Form 36 (SF-36)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)

Study description

Background summary

Background

Treatment of the inguinal hernia with a tension-free mesh has reduced the incidence of hernia recurrence. Chronic pain has become the main postoperative complication after surgical inguinal hernia repair, especially following the Lichtenstein technique. Preliminary experiences with a soft mesh positioned in the preperitoneal space (PPS) either by transinguinal preperitoneal (TIPP) or total extraperitoneal (TEP) approach, showed promising results considering the reduction of postoperative chronic pain. TEP and Lichtenstein are currently preferred techniques in guidelines worldwide. However, the ongoing evolution of surgical innovations for inguinal hernia repair led to an open direct approach with preperitoneal mesh position. Based on the ‘open’ (or anterior) TIPP procedure, another preperitoneal repair was developed: the transrectus sheath preperitoneal (TREPP) mesh repair, which comprises nine surgical steps.

Methods

The TREPPoLi trial is a prospective multicenter randomised clinical trial comparing TREPP versus Lichtenstein from patients’, societal- and from hospital perspectives. Patients will be randomly allocated to anterior inguinal hernia repair according to the TREPP mesh repair or Lichtenstein’s procedure in one of the participating expertise centers. All patients with a primary unilateral inguinal hernia, eligible for operation, will be invited to participate in the trial. The primary outcome measure will be differences in chronic postoperative inguinal pain (CPIP) of TREPP and Lichtenstein. Secondary outcome measures will be serious adverse events (SAEs), recurrence, return to daily activities (for example work), operative timeand costs. Alongside the trial a health status study and quantitative sensory testing (QST) will be

performed. To demonstrate that inguinal hernia repair according to the TREPP technique compared with Lichtenstein reduces the amount of patients with CPIP from 12% to 6%, (a 50% decrease) a sample size of 952 patients is required (two-sided test, α = 0.05, 90% power), one group of 476 patients will be randomised to TREPP and the other 476 patients will be randomised to Lichtenstein's technique. The trial was conducted warranting the risk for bias in line with the Cochrane Handbook suggestions and advices.

Conclusion

The TREPPoLi trial aims to evaluate the TREPP and Lichtenstein from patients' perspective.All outcomes will be evaluated in line with verified patient reported outcomes (vPRO's) and will focus on the amount of patients with CPIP and health status.. It is hypothesized that the TREPP technique may reduce the amount of patients with CPIP compared to the Lichtenstein procedure and that the TREPP may be easier to learn.

Trial registration: in progress.

Trial status: not started

Trial supervision: professor J.P.E.N. Pierie, MD, PhD, surgeon at Medisch Centrum Leeuwarden,and G.G. Koning, MD, PhD, surgeon at Noordwest Ziekenhuisgroep, the Netherlands on behalf of HeelkundeFriesland.nl

Study objective

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

Study design

- First visit: inclusion, baseline measurements

- 6 weeks postoperative: VAS and physical examination.

- 6 months postoperative: questionnaires and QST.

- 1 year postoperatively: questionnaires and QST

Intervention

TREPP (interventie, zie ook het artikel the nine steps of TREPP op PubMed)

Lichtenstein (controle interventie)

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Participant inclusion criteria

1. Men and women with a symptomatic primary unilateral inguinal hernia

2. Aged 18 years and over

3. ASA classification 1-3

4. Signed informed consent

Exclusion criteria

Participant exclusion criteria

1. Previous preperitoneal operations (e.g. prostatectomy, Caesarean section)

2. Bilateral hernias

2. Recurrent hernias

3. ASA classification

4. Incarcerated hernias (acute)

5. psychiatric disease, or other reasons making follow-up or questionnaires unreliable

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	1000
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5881
NTR-old	NTR6054
Other	ISRCTN14511362 : 24928

Study results

Summary results
TREPP in 9 steps (Akkersdijk et al, Int J Surgery 2016: 150-54)

Protocol will be published prior to the start of the trial