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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23859

Bron
Nationaal Trial Register

Verkorte titel
the TREPPoLi trial

Aandoening

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

Ondersteuning

Primaire sponsor: Stichting Adriaan Metius
Cooperatie Heelkunde Friesland
Medisch Centrum Leeuwarden
Overige ondersteuning: Stichting Adriaan Metius
http://www.adriaanmetiusstichting.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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, $\alpha = 0.05$, 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

Doel van het onderzoek

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

Onderzoeksopzet

- First visit: inclusion, baseline measurements

- 6 weeks postoperative: VAS and physical examination.

- 6 months postoperative: questionnaires and QST.

- 1 year postoperatively: questionnaires and QST

Onderzoeksproduct en/of interventie

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

Lichtenstein (controle interventie)

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5881
NTR-old	NTR6054
Ander register	ISRCTN14511362 : 24928

Resultaten

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

Protocol will be published prior to the start of the trial