Study protocol for a randomised clinical trial comparing TREPP versus Lichtenstein*s technique in Inguinal hernia patients

Published: 17-12-2018
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To asses the hypothesis that chronic postoperative inguinal pain occurs less in patients treated with the TREPP technique

Ethical review	Not approved
Status	Will not start
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45767

Source
ToetsingOnline

Brief title
TREPPoLi Trial

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Adriaan Metiusstichting

Intervention

Keyword: Hernia, Inguinal, Lichtenstein, TREPP

Outcome measures

Primary outcome

Chronic postoperative inguinal pain

Secondary outcome

Secondary outcomes are complications, recurrences, sexual complaints, bleeding,

time of return to daily activities and operating time.

Study description

Background summary

The main postoperative complication of inguinal hernia surgery has become chronic postoperative inguinal pain (CPIP), especially present after the Lichtenstein procedure, which is to this day the preferred open technique in the Netherlands and worldwide. New techniques aimed at lowering the percentage of patients who develop CPIP are showing promising first results. One of the conditions of a new technique is that it has to be easy to learn and teach. A new procedure that most likely meets these criteria is the TREPP (transrectus sheath preperitoneal) mesh repair. This sizeable randomized trial compares the TREPP technique to the Lichtenstein's procedure. The TREPPoLi trial aims to contribute to the question: *what*s best for patients with a clinically evident, unilateral inguinal hernia, TREPP or Lichtenstein?*

Study objective

To asses the hypothesis that chronic postoperative inguinal pain occurs less in patients treated with the TREPP technique

Study design

TREPPoLi is a multicenter randomised clinical trial (ISRCTN14511362) comparing TREPP versus Lichtenstein from the patients* perspective next to societal- and hospital perspective. All consecutive patients with a primary unilateral inguinal hernia, eligible for operation, will be invited to participate in the trial. Patients will be randomly allocated to the TREPP mesh repair or to

Lichtenstein*s procedure in one of the participating expertise centers, after written informed consent is obtained. The primary outcome measure will be presence of chronic postoperative inguinal pain (CPIP) of the TREPP and Lichtenstein patients, measured after 6 months. The total follow-up period is 1 year.

Intervention

TREPP or Lichtenstein

Study burden and risks

Two extra visits to the outpatient department as well as multiple questionnaires and physical examination.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adults with a clinically apparent primary unilateral inguinal hernia
Age > 18 years
ASA classification 1-3
Signed informed consent

Exclusion criteria

Recurrent inguinal hernia
bilateral inguinal hernia
ASA class 4
Acute incarcerated inguinal hernia
psychiatric disease or other reasons making follow-up or questionnaires unreliable
previous preperitoneal surgery (e.g. radical prostatectomy)

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	750
Type:	Anticipated

Ethics review

Not approved

Date:	17-12-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
Other	14511362
CCMO	NL65672.099.18