The treatment of recurrent inguinal hernias after posterior repair

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The aim of this study is to evaluate the safety and the outcomes of laparoscopic correction of a recurrent inguinal hernia after previous repair.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON34618

Source
ToetsingOnline

Brief title
TRIP

Condition

- Connective tissue disorders (excl congenital)
- Soft tissue therapeutic procedures

Synonym
groin hernia, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: sponsoring voor dit onderzoek zal aangevraagd worden bij SKWOS (stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis)

Intervention

Keyword: hernia, inguinal, posterior, recurrent

Outcome measures

Primary outcome

Outcomes

To evaluate the safety of a laparoscopic correction of a recurrent hernia after

previous posterior hernia repair, the following outcomes will be assessed:

• Complications during surgery, such as collateral damage or conversion

• Complications after surgery, such as wound infection, hematoma or seroma

• Pain or discomfort in the groin and possible restrictions in daily activities

• Presence of a recurrence

• Presence of a port site hernia

• Days of admission

Secondary outcome

none

Study description

Background summary

Inguinal herniorrhaphy is the most common operation performed by a general surgeon. Annually over 20 million groin hernias are repaired worldwide. Inguinal hernia repairs account for 10-15% of all general surgical procedures. There are many different surgical techniques described in the literature for hernia repair, divided in open and laparoscopic repairs. Most techniques include placement of a tension-free mesh to cover the defect. This mesh can be positioned in two ways; it can be placed anteriorly of the defect, or posteriorly of the defect.
During the laparoscopic technique the defect is approached from the intra-abdominal side and the tension-free mesh is positioned posteriorly of the

defect. The laparoscopic technique has gained increasing popularity the last couple of years due to promising results, such as lower rates of post-operative pain, rapid return to normal activities and a lower incidence of infection. The most common used methods of repairing an inguinal hernia laparoscopicly are the transabdominal pre-peritoneal (TAPP) and the totally extraperitoneal technique (TEP). So far, neither technique seems to be superior to the other. There are no statistical differences found between the two techniques in the literature with regards to recurrence rates, operating time, complications and time to return to normal activities. Some suggest that the TEP procedure is technically more challenging and requires more procedures before one becomes an experienced operator. However, for both procedures the learning curve takes between 30 and 100 procedures to become experienced.
The recurrence rate after laparoscopic repair of a primary hernia is about 1-3% and is comparable to open conventional techniques. There is still controversy about the technique how to repair a recurrent hernia after previous laparoscopic repair. The laparoscopic approach is usually a more difficult operation, requiring a profound knowledge of the anatomy of the groin and great surgical experience. Some prefer an anterior approach over a posterior approach. The posterior approach is considered to be more difficult, due to the scarring intra-peritoneally that has occurred following the previous posterior approach and the possible increase in complication.
From 1993 onwards, 100-200 laparoscopic inguinal hernias repairs are done annually at the Slotervaartziekenhuis. Approximately 50 patients had a recurrent inguinal hernia after previous posterior repair, of which some had their previous posterior repair done elsewhere. The aim of this retrospective study is to evaluate our results and analyze the safety of the laparoscopic repair of a recurrent inguinal hernia after previous posterior repair.

Study objective

The aim of this study is to evaluate the safety and the outcomes of laparoscopic correction of a recurrent inguinal hernia after previous repair.

Study design

Method
All patients that underwent laparoscopic repair of a recurrent hernia after previous hernia repair in the Slotervaartziekenhuis are identified in a database. In this database all patients are set out who were laparoscopicly operated on an inguinal hernia in our hospital since 1993. All operations are done by one single surgeon dr. B.J. Dwars, or under his supervision. The patients will be approached by telephone and invited to visit our outdoor patient clinic. During this visit we will evaluate the following outcomes by a short questionnaire, a physical examination and by a potential ultrasound of the abdomen:
• Complications after surgery, such as wound infection, hematoma or seroma

(also evaluated by file examination)
• Pain or discomfort in the groin and possible restrictions in daily activities. The pain in the groin will be assessed by a Visual Analogue Scale. The restrictions in daily activities will be assessed by a 3-point Likert scale.
• Presence of a recurrence by physical examination (and in case of doubt by an additional ultrasound of the abdomen)
• Presence of a port site hernia by physical examination (and in case of doubt by an additional ultrasound of the abdomen)
We will also examine the patient*s file and the following aspects will be studied:
• Complications during surgery, such as collateral damage or conversion
• Complications after surgery, such as wound infection, hematoma or seroma
• Days of admission

Data
Every participant will receive a code, including three letters and three numbers. The three letters will refer to the hospital where the patient is included, in this case SLZ. The three numbers will refer to the number of the patient. The first patient will receive the code SLZ001 and so on.
A key document will be generated, in which is states which code refers to which patient. This document will be kept at a secured computer. The two researchers only will have access to this computer. For every patient a document is generated at this secured computer. In this document the outcome of the questionnaire, the physical examination, the file analysis and the possible abdominal ultrasound will be saved. The paper forms will be destroyed.

Power-analysis
Not applicable.

Statistical analysis
In this descriptive retrospective analysis we will evaluate our results after laparoscopic repair of a recurrent inguinal hernia after posterior repair. We will assess the prevalence of complications and calculate the mean of the VAS-score and the Likert scale. These numbers will be calculated in Windows 7 XL Office.

Inclusion criteria
• Laparoscopic correction of a recurrent inguinal hernia after posterior repair done at the Slotervaartziekenhuis from 1993 onward.

Exclusion criteria
• none

Study burden and risks

The patient will be requested to visit the outdoor patient clinic at least

once. This visit will take approximately 20 mintues in time. During this visit a questionnaire is answered and a physical examination is done. There are no risks for the patient participating in this study. The possible knowledge of having a recurrent hernia or a port site hernia might be unwanted.

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

patients who had laparoscopic recurrent inguinal hernia repair, after previous posterior repair

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL34519.048.10