The value of telephone survey in the follow-up of hernia patients.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON37987

Source
ToetsingOnline

Brief title
Q-Phone Pilot

Condition

- Soft tissue therapeutic procedures

Synonym
hernia

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: follow-up, hernia, telephonic survey

Outcome measures

Primary outcome

Operated groin

Complaints: Yes / No. If so? Which?

Self noticed something: Yes / No

Coughing, sneezing, press: Yes / No

Blow on back of hand: Yes / No

On physical examination the presence of recurrence: Yes / No

Any presence of echo recurrences: Yes / No

Port side hernia

Complaints: Yes / No. If so? Which?

Self noticed something: Yes / No

Coughing, sneezing, press: Yes / No

Blow on back of hand: Yes / No

On physical examination the presence of recurrence: Yes / No

Any presence of echo recurrences: Yes / No

Secondary outcome

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Study description

Background summary

Groin hernia therapie is the most common operation performed by general surgeons. Annually, over 20 million groin hernias are repaired worldwide. The long-term complications of a groin hernia are mainly recurrence and pain. The recurrence rate of a primary inguinal hernia, after open or laparoscopic repair, is between 1-3%. The laparoscopic technique is getting more support, given the presumably better outcomes regarding postoperative pain, faster recovery after surgery and a lower risk of wound infections. The most common laparoscopic techniques for inguinal hernia repair are transabdominal preperitoneal (TAPP) repair and totally extraperitoneal (TEP) repair. Up till now, neither of these techniques is superior. In literature no significant differences are described considering recurrence rates.

Retrospective and prospective studies of laparoscopic hernia correction go back to the early 1990s. Most of these studies do not explain how follow-up was conducted. For example, it is unclear where physical examination has taken place in order to detect recurrences. It is now clear that recurrence depends not only on the surgical expertise or surgical technique, but also on the length and method of follow-up. Long-term follow-up in this population remains difficult, since there is a benign disease, patients are asymptomatic or died. That is why patients disappear in the follow-up. The number of patients that are lost because of this, will affect the outcome of the follow-up.

There are several studies on follow-up in hernia patients. Kald and co-workers concluded that a method of follow-up by questionnaire, followed by selective physical examination (only patients with symptoms / recurrence of the questionnaire were seen again) is only suitable to detect symptomatic recurrences. Asymptomatic recurrences remained undiscovered. Vos and Simons (1994) compared a questionnaire on paper with an outpatient physical examination, with the result that half of the recurrences in a questionnaire without a physical examination were not detected. Besides, there was a large number of false positives (8 of 15). The conclusion of the study was that the only reliable way of follow-up is outpatient physical examination.

In literature there are different types of recurrences described, namely symptomatic, asymptomatic and occult recurrences. The number of asymptomatic and occult inguinal hernias is unclear, because these patients do not report themselves at the policlinic. It is therefore important to find a good follow-up method for hernia patients, so that all recurrences, including the asymptomatic and occult, will be discovered. There is no evidence in literature that the telephone survey is a valid method to follow-up operated hernia patients. More targeted questions can be asked in the telephone survey. It is a practical and time saving way to approach a large amount of patients. In the

guideline 2009, the European Hernia Society emphasizes the usefulness of the accurate follow-up, after inguinal hernia surgery.

In the Slotervaart Hospital we have access to a large patient database (3000). All of these patients underwent surgery by the same surgeon and with the same technique (TAPP). This study is a pilot study to examine the value of the telephone survey assessed by comparing it to the gold standard: physical examination. The purpose of this pilot study is to validate a telephone survey to follow-up patients that underwent a laparoscopic hernia surgery.

The literature describes a hernia recurrence of 2%, where part of which is unknown. To detect telephonic recurrence in hernia patients, even if it shows no symptoms, there is a large number of patients (at least 600) necessary to obtain a good confidence interval. There has been chosen to do a pilot study first because the number false positives must be observed.

Study objective

The aim of this pilot study is to validate the telephonic survey to evaluate the outcomes of laparoscopic correction of an inguinal hernia after previous repair.

Hypothesis: The Q-Phone can detect telephonic recurrence in patients who underwent laparoscopic correction of an inguinal hernia, even if they do not give symptoms.

Study design

All patients that underwent laparoscopic correction of an inguinal hernia by TAPP done at the Slotervaart Hospital from 1993 onward are identified in a database.
All procedures were performed by, or supervised by an experienced surgeon, dr. B.J. Dwars.
The database will be a random selected group of 250 patients. These patients will be approached by telephone to inform them about the study. If patients are interested in participating, we will send the patient a leaflet with information about the study with a inform consent which the patient can return by the enclosed envelope. After ten days the patient will be re-contacted by telephone and will be asked if he or she wants to cooperate in the study. If patients want to participate, a telephone and outpatient appointment will be made.

The survey done by telephone contains the following questions:

1. Do you have symptoms in your operated groin? If so, what?

2. Did you notice anything in your operated groin? (yes / no)
3. Do you notice something in the operated groin when coughing, sneezing, pressing? (yes / no)
4. Could you please stand up and blow on the back of your hand? Then, please with your other hand touch your operated groin. Do you feel something in your operated groin? (yes / no)
5. Do you have symptoms of the port-side insertions in your abdomen? If so, what?
6. Did you notice anything at the insertion of the port-side? (yes / no)
7. Do you notice something at the port-side insertions when coughing, sneezing or straining?(yes / no)
8. Could you please stand up and blow on the back of your hand? Then, please with your other hand touch your port-side insertions. Do you feel something at your port-side insertion? (yes / no)

Patients with bilateral inguinal hernias will get about each groin a separately question.

At the clinic we will evaluate the following outcomes through questions and a physical examination:
- The questions of the telephone survey will be repeated
- Presence of a recurrence by physical examination
- Presence of a port site hernia by physical examination

If there is doubt about the presence of recurrence or port site hernia, an abdominal ultrasound will be made.

All these results will be listed on an outcome form.

Study burden and risks

There are in this study no disadvantages, except that the patient has an additional visit to our outpatient clinic. This time load can be seen as a disadvantage.

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

Laparoscopic correction by TAPP (transabdominal pre-peritoneal technique) of an inguinal hernia done at the Slotervaartziekenhuis from 1993 onward

Exclusion criteria

Recurrence hernia after primary correction hernia wherefor medical consultation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-09-2011
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2011
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	12-12-2012
Application type:	Amendment
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	NL37042.048.11