

Patient Reported Outcomes in INGuinal Hernia Surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22857

Source

NTR

Brief title

PRO-ING Study

Health condition

Inguinal Hernias

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

PROs after inguinal hernia repair

Secondary outcome

Chronic pain after inguinal hernia repair

Study description

Background summary

Yearly, 30.000 inguinal hernia repairs are performed in the Netherlands. Surgical treatment of an inguinal hernia is successful in the majority of cases. However, 10-12% of the patients after inguinal hernia repair develop chronic pain. This has a negative impact on quality of life, daily activities and the number of days sick leave.

Discussion remains about the way of recovery and etiology of developing chronic pain after inguinal hernia repair. Patient-Reported-Outcomes Measures (PROMs) are believed to have a growing significant meaning in the treatment of any condition or disease, including inguinal hernias. However, this requires knowledge on the patient-reported-outcomes first. With the PRO-ING Study we want to study the patient-reported-outcomes after open and laparoscopic inguinal hernia surgery, and the etiology and incidence of chronic pain.

The PRO-ING Study is a multicenter prospective cohort study, that will be conducted in five hospitals in the North of the Netherlands. Patients visiting the outpatient clinic will be given the study information. In case patients want to participate an informed consent form can be returned. After surgery patients will be sent 4 follow-up questionnaires: at 6 weeks, 3 months, 6 months and 1 year. At one year follow-up, patients that have a NRS of 4 or more will be invited to the outpatient clinic for further analysis. Baseline criteria on patient characteristics, hernia specifics and operation details, together with the patient-reported-outcomes, will be collected in a database.

Study objective

The hypothesis of this study is that PROMs have a significant meaning in the management of patients undergoing inguinal hernia repair.

Study design

Start of the study: January 2019. Inclusion until February 2020. Follow-up until February 2021.

Intervention

Patient Reported Outcomes Measurements / Questionnaires

Contacts

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Eligibility criteria

Inclusion criteria

Male adult patients with a primary inguinal hernia undergoing either open or laparoscopic repair

Exclusion criteria

Female, insufficient understanding of the Dutch language, recurrent hernias, emergency hernia repair

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	440
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 12-11-2019

Application type: First submission

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	NL8149
Other	METC UMCG : METc 2018/500

Study results