

Patient Reported Outcomes in INGuinal Hernia Surgery

Gepubliceerd: 12-11-2019 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22857

Bron

NTR

Verkorte titel

PRO-ING Study

Aandoening

Inguinal Hernias

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PROs after inguinal hernia repair

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Patient Reported Outcomes Measurements / Questionnaires

Contactpersonen

Publiek

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Wetenschappelijk

UMCG Groningen
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 01-01-2019
Aantal proefpersonen: 440
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 12-11-2019
Soort: Eerste indiening

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	NL8149
Ander register	METC UMCG : METc 2018/500

Resultaten