

The impact of decision aids in patients with gallstones, an inguinal hernia, knee osteoarthritis and hip osteoarthritis

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Primary hypothesis Our primary hypothesis is that the implementation of decision aids for patients who suffer from symptomatic cholecystolithiasis, inguinal hernia, knee or hip osteoarthritis will result in better patient reported outcomes....

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

Samenvatting

ID

NL-OMON28916

Bron

Nationaal Trial Register

Aandoening

Shared decision making, Hernia inguinal, knee osteoarthritis, hip osteoarthritis, gallstones, treatment, surgery

Ondersteuning

Primaire sponsor: Radboud University Medical Center

Overige ondersteuning: Radboud University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint will be patient reported outcomes of patients with and without decision aid after 0, 3, 6 and 12 months

Toelichting onderzoek

Achtergrond van het onderzoek

This is a multi center, prospective cohort study. In this study we would like to determine the impact of decision aids, tools with balanced and patient adjusted information about the harms and benefits of treatments (surgery or no surgery), in standardized care in patients with gallstones, inguinal hernia, hip- and knee osteoarthritis. Patients will all be recruited in the Netherlands.

We aim to evaluate the patient reported outcomes in patients with and without a decision aid. Secondly, we aim to determine the effect on of decision aids on operation rate, satisfaction and health care costs.

After inclusion of the patients and 12 months follow-up, statistical analysis will be carried out using IBM SPSS

Doel van het onderzoek

Primary hypothesis

Our primary hypothesis is that the implementation of decision aids for patients who suffer from symptomatic cholecystolithiasis, inguinal hernia, knee or hip osteoarthritis will result in better patient reported outcomes.

Secondary hypothesis

Secondarily we hypothesized that there is a significant reduction in operation rate. Patients will be more satisfied and implementation of decision aids is cost-effective.

Onderzoeksopzet

t = 0 months

Decision Aid

Questionnaires:

Patient demographics

EQ5D

GSL / EuraHS / HOOS / KOOS

SDM-9

Treatment Preference

t = 3 months

Questionnaires:

EQ5D

GSL / EuraHS / HOOS / KOOS

SDM-9

Satisfaction and Painscore

t = 6 months

Questionnaires:

EQ5D

GSL / EuraHS / HOOS / KOOS

SDM-9

Satisfaction and Painscore

Onderzoeksproduct en/of interventie

Decision Aids:

Tools with balanced, patient adjusted information about the harms and benefits of treatments. Decision aids facilitate SDM.

Questionnaires:

- EQ5D

- Gallstone Symptom List (GSL)

- EuraHS

- Shared Decision Making Questionnaire - 9 (SDM-9)
- Collaborate
- SFHLQ
- HOOS
- KOOS
- Treatment preference, satisfaction and painscore

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years of age or older
- referred for surgical consultation with symptomatic cholecystolithiasis, inguinal hernia, knee osteoarthritis or hip osteoarthritis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Complicated gallstone disease
- Mentally incompetent

- Insufficient knowledge of Dutch language

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-01-2019
Aantal proefpersonen: 3500
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 14-11-2018
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	NL7400
NTR-old	NTR7616
Ander register	Commissie Mensgebonden Onderzoek : 2018-4815

Resultaten