

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

No registrations found.

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

Summary

ID

NL-OMON28916

Source

Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Radboud University Medical Center

Source(s) of monetary or material Support: Radboud University Medical Center

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Operation rate in patients with and without decision aid.
- Patient satisfaction of patients with and without decision aid after 0, 3, 6 and 12 months
- Healthcare costs of patients with and without decision aid.

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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 pain score

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- Complicated gallstone disease

- Mentally incompetent
- Insufficient knowledge of Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	3500
Type:	Anticipated

Ethics review

Positive opinion	
Date:	14-11-2018
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	NL7400
NTR-old	NTR7616
Other	Commissie Mensgebonden Onderzoek : 2018-4815

Study results