

# The Impact of Decision Aids in Gallbladder and Inguinal Hernia Surgery

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22243

### Source

Nationaal Trial Register

### Health condition

Decision Aids, Shared Decision Making, Gallstones, Inguinal Hernia, Surgery, treatment preferences, PROMS

## Sponsors and support

**Primary sponsor:** Radboud University Medical Center Nijmegen

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

## Intervention

## Outcome measures

### Primary outcome

The main study endpoint will be the change in patients treatment preference before and after the decision aid.

### Secondary outcome

- The difference between treatment preference of physician and patient after the decision

aid.

- The difference between physicians and patients treatment preferences and final shared decision.
- Patient satisfaction after 6 months.
- Patient Reported Outcomes after 6 months.
- Operation rate

## Study description

### Background summary

This study is a single centre, prospective cohort study. In this single centre decision aids, tools with balanced, patient adjusted information about the harms and benefits of treatments (surgery or no surgery), are standardized care for patients with gallstones and inguinal hernia. Patients will all be recruited in the Netherlands.

We aim to determine the change in patient treatment preference before and after the decision aid. Secondly, we research patient reported outcomes with questionnaires after 3 and 6 months.

After inclusion of 350 patients and 6 months follow-up, statistical analysis will be carried out using IBM SPSS.

### Study design

t = 0 months

Decision Aid

Questionnaires:

Patient demographics

EQ5D

GSL / EuraHS

SDM-9

Treatment Preference

t = 3 months

Questionnaires:

EQ5D

GSL / EuraHS

SDM-9

Satisfaction and Painscore

t = 6 months

Questionnaires:

EQ5D

GSL / EuraHS

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) Or EuraHS

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- 18 years of age or older
- referred for surgical consultation with gallstones or inguinal hernia

### **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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	08-10-2018
Enrollment:	350
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	27-09-2018
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	NL7292
NTR-old	NTR7501
Other	Commissie Mensgebonden Onderzoek : 2017-3972

## Study results