

The validation a decision rule for the indication of gallbladder surgery in people with gallstones.

No registrations found.

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

Summary

ID

NL-OMON24368

Source

Nationaal Trial Register

Brief title

SUCCES

Health condition

Uncomplicated cholecystolithiasis

Gallstones

Cholecystectomy

Post-cholecystectomy symptoms

Ongecompliceerde cholecystolithiasis

Galstenen

Cholecystectomie

Symptomen na cholecystectomie

Sponsors and support

Primary sponsor: Radboud University Medical Center

Source(s) of monetary or material Support: Innovatiefonds zorgverzekeraars

Intervention

Outcome measures

Primary outcome

The predictive validity, external validity and the sensitivity and specificity of the decision rule with as outcome a pain-free patient after 6 months.

Secondary outcome

- The proportion of patients fulfilling 3 or more criteria of the decision rule and scheduled for cholecystectomy and the proportion in those not scheduled.
- The proportion of patients fulfilling 3, 4 or 5 criteria of the decision rule, scheduled for cholecystectomy and pain-free.
- The symptoms of patients at baseline predicting to be painfree after cholecystectomy.
- The proportion of patients with uncomplicated cholecystolithiasis and abdominal symptoms that has a BMI >25 and the proportion with BMI >30
- The difference in symptom change, after six months follow-up between the group of patients that received cholecystectomy and those without operation
- Description of additional health care consumption in patients not scheduled for surgery, i.e. diagnostic tests and therapeutic interventions within six months of first outpatient clinic visit
- Description of the aspect and wall thickness of the gallbladder wall at ultrasound
- Description of the pathological report of the gallbladder (providing that the patient had an operation and pathological examination of the gallbladder is done)

Study description

Background summary

This study is a prospective, multicentre cohort study. In which we validate the decision rule for surgery indication in patients with uncomplicated cholecystolithiasis;

All adult patients referred to the surgical outpatient clinic for gallstones will be considered for inclusion. Patients will all be recruited in The Netherlands.

They will be phoned by one of our researchers and asked if they want to participate in the study.

After the first outpatient clinic visit ($t=0$), the patient characteristics, EQ-5D, Short Form - Health and Labour Questionnaire, Izbicki Pain Score, Gastro-Intestinal Quality of Life Index and Gallstone Symptom List will be taken via e-mail.

After 3 ($t=3$) and 6 months ($t=6$) the patients will receive the questionnaires again. In between some patients will be treated by means of a cholecystectomy and others won't get treatment (still observational).

After this, data management and statistical analysis will be carried out using IBM SPSS statistical software package version 22.0 (SPSS inc., Chicago, IL).

Study design

$t=0$ months

-Patient characteristics:

- sex
- age
- BMI
- ethnic background
- smoking (packages per week)
- alcohol use (glasses per week)
- use of painkillers
- history or current treatment of: high blood pressure, high cholesterol or diabetes.
- other diseases
- history of operations or gastroscopy
- other medicine used besides painkillers

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

Gastro-Intestinal Quality of Life Index

Gallstone Symptom List

t = 3 months

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

Gastro-Intestinal Quality of Life Index

Gallstone Symptom List

t=6 months

Treatment, operation report, pathology, report

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

Gastro-Intestinal Quality of Life Index

Gallstone Symptom List

Intervention

Questionnaires:

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

Gastro-Intestinal Quality of Life Index

Gallstone Symptom List

Contacts

Public

Huispost 618, Postbus 9101

Carmen Latenstein
Nijmegen 6500 HB
The Netherlands
06-19402554

Scientific

Huispost 618, Postbus 9101

Carmen Latenstein
Nijmegen 6500 HB
The Netherlands
06-19402554

Eligibility criteria

Inclusion criteria

- 18 years of age or older, and
- with ultrasonically proven, uncomplicated cholecystolithiasis, and
- referred for surgical consultation

Exclusion criteria

- History of complicated cholelithiasis (i.e. choledocholithiasis, acute cholecystitis, biliary pancreatitis or cholangitis)
- Current schizophrenia, memory deficiency, or any other disorder that predispose them to unreliable questionnaire responses;
- Mentally incompetent;
- Insufficient knowledge of the Dutch language;
- Known pregnancy

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:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion	
Date:	12-06-2018
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	NL7069
NTR-old	NTR7267
Other	Commissie Mensgebonden Onderzoek : 2017 3306

Study results