# The validatation 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 fullfilling 3, 4 or 5 criteria of the decision rule, scheduled for cholecystectomy and pain-free.
- The symptoms of patients at baseline prediciting 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.

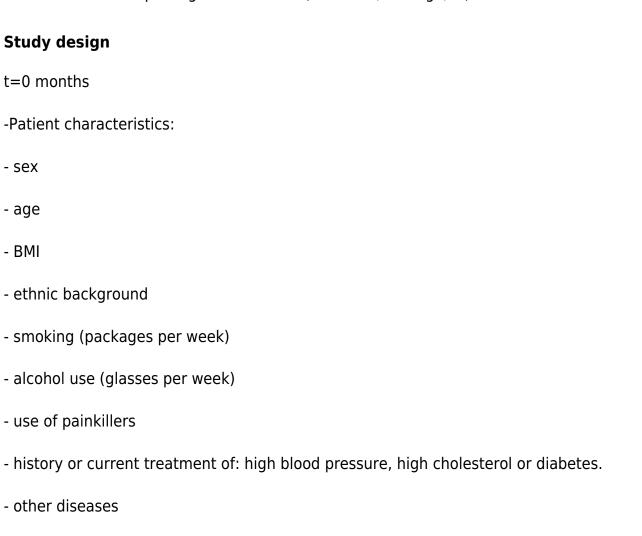
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They will be phoned by one of our researchers and asked if they want to participate in the study.

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 cholecystecomy 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).



- history of operations or gastroscopy
- other medicine used besides painkillers

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

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Gastro-Intestinal Quality of Life Index Gallstone Symptom List t = 3 monthsEQ-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**

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# **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**