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

Gepubliceerd: 12-06-2018 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON24368

Bron
Nationaal Trial Register

Verkorte titel
SUCCES

Aandoening

Uncomplicated cholecystolithiasis
Gallstones
Cholecystectomy
Post-cholecystectomy symptoms

Ongecompliceerde cholecystolithiasis
Galstenen
Cholecystectomie
Symptomen na cholecystectomie

Ondersteuning

Primaire sponsor: Radboud University Medical Center
Overige ondersteuning: Innovatiefonds zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Questionnaires:

EQ-5D

Short Form - Health and Labour Questionnaire

Izbicki Pain Score

Gastro-Intestinal Quality of Life Index

Gallstone Symptom List

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years of age or older, and

- with ultrasonically proven, uncomplicated cholecystolithiasis, and

- referred for surgical consultation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2018
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	NL7069
NTR-old	NTR7267
Ander register	Commissie Mensgebonden Onderzoek : 2017 3306

Resultaten