Scrutinizing the (in)efficient use of cholecystectomy.

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Stepwise selection of patients with cholecystolithiasis for cholecystectomy is not inferior to usual care with respect to the patient reported outcome, but attributes to a more appropriate use of care and provides a basis for a lower number of...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27558

Bron
Nationaal Trial Register

Verkorte titel
SECURE

Aandoening

Cholecystectomy, gallstones, randomized trial, variation in practice

Cholecystectomie, galstenen, praktijkvariatie, gerandomiseerde studie.

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of patients being pain free at 12 months of follow-up. Pain free is defined as a visual analogue scale (VAS; validated pain score) less than or equal to 4 over the last two weeks before evaluation.

Toelichting onderzoek

Achtergrond van het onderzoek

In this prospective study we will examine the effectiveness of usual care with a restrictive care strategy using a standardized work-up with stepwise selection for cholecystectomy in patients with ultrasound proven gallstones and abdominal complaints over a 12 month period.

Doel van het onderzoek

Stepwise selection of patients with cholecystolithiasis for cholecystectomy is not inferior to usual care with respect to the patient reported outcome, but attributes to a more appropriate use of care and provides a basis for a lower number of cholecystectomies performed.This may improve patients' health status, prevent complications, reduce health care demand and lower costs.

Onderzoeksopzet

Follow-up at 3,6,9 and 12 months after initial presentation.

Onderzoeksproduct en/of interventie

The intervention includes a standardized work-up and multistage selection for cholecystectomy. Standardization is done by strict administration of the symptoms associated with symptomatic cholecystolithiasis as reported in the Dutch national guideline Gallstones.24 In addition, the multistage selection includes an interval evaluation after every 3 months.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Having abdominal symptoms and having ultrasound proven gallstones or sludge (proven before or after referral);

2. Being referred to a surgeon for the treatment of suspected symptomatic gallstone disease;

3. Aged 18 years or older;

4. Providing informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of complicated cholelithiasis (i.e. choledocholithiasis, acute cholecystitis, biliary pancreatitis or cholangitis) since these types of patients are scheduled for elective cholecystectomy to prevent recurrence of complicated cholelithiasis rather than to prevent complaints of symptomatic cholecystolithiasis;

2. Indication for primary open cholecystectomy;

3. History of current malignancy;

4. Expected short life span of less than 12 months;

5. Suffering from severe or life-threatening systemic diseases (American Society of Anesthesiologists (ASA) class III and IV);

6. Known cirrhosis of the liver;

7. Current schizophrenia, memory deficiency, or any other disorder that predispose them to unreliable questionnaire responses;

8. Mentally incompetent;

9. Insufficient knowledge of the Dutch language;

10. Unable to read due to blindness;

11. Known pregnancy;

12. Residence in a federal correctional institution.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	986
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL3862
NTR-old	NTR4022
Ander register	SECURE-trial : METC 2013_129
ISRCTN	ISRCT wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A