Scrutinizing the (in)efficient use of cholecystectomy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27558

Source
Nationaal Trial Register

Brief title
SECURE

Health condition

Cholecystectomy, gallstones, randomized trial, variation in practice

Cholecystectomie, galstenen, praktijkvariatie, gerandomiseerde studie.

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. The proportion of patients being pain-free after cholecystectomy;

2. The proportion of cholecystectomies;

3. The proportion of patients with complications (i.e. choledocholithiasis, acute cholecystitis, biliary pancreatitis or cholangitis) due to gallstones;

4. Changes in health status and valuation over time. Health status will be measured using generic and disease specific health status questionnaires after informed consent and after 3, 6 and 12 months;

5. Time to pain free;

6. The relation between the patients' symptoms and treatment and work performance as reported in the Health and Labour questionnaire;

7. Cost-effectiveness;

8. The proportion of complications due to the cholecystectomy.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	986
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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

Study results

Summary results
N/A