Scrutinizing (in)efficient use of cholecystectomy: a randomized trial concerning variation in practice.

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Current practice variation in selection of patients with gallbladder stones and abdominal complaints for cholecystectomy is not efficient. Here we evaluate stepwise selection for surgery to improve patient outcome and to reduce the number of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gallbladder disorders
Study type	Interventional

Summary

ID

NL-OMON45086

Source
ToetsingOnline

Brief title
SECURE

Condition

- Gallbladder disorders
- Hepatobiliary therapeutic procedures

Synonym
Cholelithiasis, gallstone disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cholecystectomy, Gallstones, Randomized trial, Variation in practice

Outcome measures

Primary outcome

- The percentage of patients 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 four weeks before evaluation.

Secondary outcome

A comparison of usual care with the restrictive strategy on:

(a) The proportion of patients being pain-free after cholecystectomy

(b) The proportion of cholecystectomies

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

(d) 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.

(e) Time to pain free

(f) The relation between the patients* symptoms and treatment and work performance

(g) Cost-effectiveness

(h) The proportion of complications due to the cholecystectomy.

(i) Patient satisfaction on result of treatment

(j) Alternative diagnostic test and treatment (additional to or replacing

cholecystectomy)

Study description

Background summary

Five to 22 percent of the adult Western population has gallstones. Among them, 13 to 22 percent becomes symptomatic during their lifetime. Cholecystectomy (gallbladder removal) is the preferred treatment option for symptomatic cholecystolithiasis (painful gallstones) today. In The Netherlands, with 16 million inhabitants, annually more than 20,000 cholecystectomies are performed against direct hospital-related costs of 80 million euro. Remarkably, gallbladder removal appears to be ineffective in 30-40% of patients. In addition, the Dutch health care insurance companies have noted a considerable practice variation in gallbladder removals in The Netherlands, attributable to a lack of evidence and to preferences that differ by surgeon.

Study objective

Current practice variation in selection of patients with gallbladder stones and abdominal complaints for cholecystectomy is not efficient. Here we evaluate stepwise selection for surgery to improve patient outcome and to reduce the number of cholecystectomies.

Study design

Randomized controlled trial

Intervention

Patients will be randomized into 2 groups. The first group comprises usual care with practice variation in performing laparoscopic cholecystectomy. The second group comprises a restrictive strategy with standardized work-up and interval evaluation with stepwise selection for laparoscopic cholecystectomy.

Study burden and risks

The gallbladder will be removed in both groups if there is a clear medical reason. A disadvantage may be that a subject prefers to be operated immediately, but because be do not know if we help the subject to get rid of his symptoms there will be a possibility that we postpone the eventual operation or drop it if the symptoms have disappeared. Another possible disadvantage of this study is that the completion of the questionnaires may

require some extra time of the subject. Subject will receive the same questionnaires at home before treatment and at 3, 6, 9 and 12 months and will be asked to return the completed questionnaires. These questionnaires relate to symptoms and wellbeing of the subjects. This will take about 15 minutes a time. Amendement: Five years after inclusion, patients will be approached to fill-out a long term follow-up questionnaire. Only patients who gave permission on the informed consent form to be contacted again (after intitial 12 months follow-up) will be send this questionnaire. The content of the questionnaire will be the same as the 12 month follow-up questionnaire supplemented with questions on (health care consumption) for gallstone symptoms or persistent symptoms after cholecystectomy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Referred to a surgeon with abdominal complaints and who have ultrasound proven gallstones or sludge (proven before or after referral)
2. Patients age 18 years or older
3. Availability of informed consent.

Exclusion criteria

1. A history of complicated cholecystolithiasis
2. Indication for primary open cholecystectomy
3. Current treatment for malignancy
4. Expected short life span of less than 12 months
5. ASA score 3 or 4
6. Pregnancy
7. Insufficient knowledge of the Dutch language
8. Mentally incompentent
9. Residence in a federal correctional institution
10. Known cirrhosis of the liver
11. Current schizophrenia, memory deficiency, or any other disorder that predispose them to unreliable questionnaire responses

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2014

Enrollment:	1038
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL43810.018.13