Laparoscopic cholecystectomy versus radiological drainage of the gallbladder in acute cholecystitis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24221

Source
Nationaal Trial Register

Brief title
CHOCOLATE

Health condition

Acute calculous cholecystitis

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis Nieuwegein
Source(s) of monetary or material Support: St. Antonius Ziekenhuis Nieuwegein

Intervention

Outcome measures

Primary outcome

1. Mortality;

2. All procedure related major morbidity (Infectious complications, cardio-pulmonary

complications, need for re-intervention, recurrent biliary disease).

Secondary outcome

1. All individual components of primary endpoint;

2. Length of hospital admission;

3. Time to full recovery;

4. Cost-effectiveness analysis.

Study description

Background summary

Acute calculous cholecystitis is a frequently encountered problem in the surgical practice and laparoscopic cholecystectomy (LC) is still the standard treatment for patients without significant comorbidity and therefore low-moderate risks on intervention. In elderly patients or patients with significant comorbidity, surgery in general is associated with higher complication rates and even mortality. Percutaneous cholecystostomy (PC) may be an alternative, and in the current surgical practice many surgeons prefer this method over LC in acute calculous cholecystitis in patients with increased risks. Because the gallbladder remains in situ, the infection can worsen mandating an emergency LC which can be even more difficult, and there is always the risk of recurrence.

The CHOCOLATE Trial is initiated to determine superiority of the laparoscopic cholecystectomy over percutaneous drainage in the treatment of acute cholecystitis in patients with increased risk. It is designed as a multi centre randomized controlled trial, including patients with acute calculous cholecystitis with increased risk (defined as APACHE score ≥6 AND ≤14). Patients will be randomized to either laparoscopic cholecystectomy or percutaneous drainage of the gallbladder. The endpoint is a combined endpoint of all procedure related morbidity and mortality with a total duration of follow up of one year.

Study objective

Laparoscopic cholecystectomy is the preferred therapy for all patients eligible for surgery with acute calculous cholecystitis.

Study design

Iclusion will approximately take two years, follow up will be one year.

An interim analysis will be performed every three months.

Intervention

1. Laparoscopic Cholecystectomy;

2. Percutaneous Cholecystostomy.

Contacts

Public
St Antonius Hospital, Department of Surgery,
P.O. Box 2500
D. Boerma
Nieuwegein 3430 EM
The Netherlands
Scientific
St Antonius Hospital, Department of Surgery,
P.O. Box 2500
D. Boerma
Nieuwegein 3430 EM
The Netherlands

Eligibility criteria

Inclusion criteria

1. APACHE-II score greater than or equal to 7 AND smaller than or equall to 14;

2. Acute calculous cholecystitis, defined according to Tokyo Guidelines;

3. Written informed consent.

Exclusion criteria

1. < 18 years of age;

2. Onset of symptoms lesser than or equal to 7 days before first presentation;

3. Already admitted to ICU;

4. Pregnancy;

5. APACHE-II score smaller than or equal to 6 OR greater than or equal to 15;

6. Acalculous cholecystitis;

7. Decompensated liver cirrhosis;

8. Mental illness prohibiting informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2011
Enrollment:	302
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-12-2010
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	NL2548
NTR-old	NTR2666
Other	VCMO Antonius Hospital Nieuwegein : R-10.30A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A