

Acute cholecystitis in high risk patients: percutaneous cholecystostomy versus laparoscopic cholecystectomy; a randomized controlled, open, parallel, superiority, multicenter trial

Published: 15-01-2011

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To demonstrate that primary LC as compared to PC is preferable with respect to morbidity and mortality in high risk surgical patients (APACHE-II score 7-14) with acute calculous cholecystitis.

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

Summary

ID

NL-OMON40048

Source

ToetsingOnline

Brief title

CHOCOLATE

Condition

- Gallbladder disorders
- Hepatobiliary therapeutic procedures

Synonym

cholecystitis, inflamed gallbladder

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: er is geen financiering voor het onderzoek. Alle deelnemende centra zijn in overleg met het initierende centrum verantwoordelijk voor hun eigen kosten; welke vrijwel geheel binnen het normale behandelspectrum vallen.

Intervention

Keyword: cholecystitis, laparoscopic cholecystectomy, percutaneous cholecystostomy

Outcome measures

Primary outcome

Combined endpoint including all major complications, need for re-intervention and mortality.

Secondary outcome

Individual components of composite endpoint, Minor complications, Difficulty of cholecystectomy, total length of hospital stay, emergency room visits, cost efficiency

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. Acute cholecystitis is not a disease confined to this population, and in elderly patients or patients with significant comorbidity, surgery in general is associated with higher complication rates and even mortality, and there is no consensus in the general surgical practice if LC actually is the treatment of choice in this patient category. In addition, LC for acute cholecystitis can be a more difficult procedure than elective LC for cholelithiasis and is associated with increased operating time, higher conversion rate and more post-operative complications in any patient category, especially in elderly patients or patients with comorbidity. Percutaneous cholecystostomy (PC) may be a more preferable method,

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. There is some evidence in the current literature regarding the safety, success rate and procedure specific technique of this procedure, but the question whether there is a place for PC in the treatment of acute calculous cholecystitis, remains unanswered.

Study objective

To demonstrate that primary LC as compared to PC is preferable with respect to morbidity and mortality in high risk surgical patients (APACHE-II score 7-14) with acute calculous cholecystitis.

Study design

Multi center randomized controlled trial

Intervention

The study has two treatment arms; arm one will be treated with laparoscopic cholecystectomy, arm two with percutaneous cholecystostomy.

Study burden and risks

Risks of participation are no greater or different from the general treatment of acute calculous cholecystitis.

Burden of participation is a total of 12 follow up phone calls that would normally not take place.

Benefit of participation is treatment within 24 hours, and, when assigned to the LC-arm, surgery by a specialised GI-surgeon.

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

APACHE-II score ≥ 7 AND ≤ 14

Acute calculous cholecystitis

Written informed consent

Exclusion criteria

Onset of symptoms ≥ 7 days before first presentation

Already admitted to ICU

Pregnancy

< 18 Years of age

Acalculous cholecystitis

Decompensated liver cirrhosis

Mental illness prohibiting informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	284
Type:	Actual

Ethics review

Approved WMO	
Date:	15-01-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	12-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	20-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	28-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	30-06-2011
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	04-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	16-08-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	02-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	16-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	07-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	08-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	08-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	18-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	17-07-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	06-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	19-12-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	20-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

CCMO

ID

NL33662.100.10