Perioperative antibiotic use in the treatment of acute inflammation of the gallbladder.

No registrations found.

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

Summary

ID

NL-OMON24030

Source
Nationaal Trial Register

Brief title
PEANUTS II

Health condition

Acute calculous cholecystitis

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: St. Antonius Research Foundation

Intervention

Outcome measures

Primary outcome

The primary endpoint is a composite endpoint consisting of all postoperative infectious complications occurring during the first 30 days after surgery

Secondary outcome

The secondary endpoints include all the individual components of the primary endpoint and, in addition, all other complications, the total postoperative duration of hospital stay and the total costs.

Study description

Background summary

Rationale

It is current practice to administer a single prophylactic dose of intravenous antibiotics, 15-30 minutes prior the incision, in patients who undergo an emergency cholecystectomy. In current literature, high level evidence is available that in patients undergoing elective cholecystectomy for uncomplicated cholelithiasis, prophylactic antibiotics do not decrease the incidence of postoperative infections. Recent studies, as well as our own data, show that extended treatment with antibiotic prophylaxis doesn’t benefit the outcome in terms of surgical site infections and does increase duration of hospital stay and costs. Furthermore the use of unnecessary antibiotics leads to an increased resistance to antibiotics. The remaining question is whether even a single dose antibiotic prophylaxis is beneficial in patient with acute cholecystitis who undergo laparoscopic cholecystectomy.

Objective

This study is designed to demonstrate whether or not patients who undergo cholecystectomy for acute calculous cholecystitis, benefit from preoperative antibiotic prophylaxis

Study design

A randomized controlled, multicenter, open-label non-inferiority trial

Study population

All patients with acute calculous cholecystitis undergoing emergency cholecystectomy over 18 years of age.

Intervention

A. No antibiotic treatment

B. A single dose of 2000 mg of cefazolin, 15-30 minutes prior to surgery

Main study parameters/endpoints

The primary outcome measure is the development of postoperative infections (surgical site and distant infections) within 30 days after surgery. Secondary endpoints are the individual infections, other postoperative complications, duration of hospital stay and total costs.

Study objective

The absence of antibiotic prophylaxis would not lead to an increase of postoperative infectious complications

Study design

Inclusion of patients will take approximately three years. Total duration of follow up is one month.

Intervention

- 2000 milligrams of first generation cephalosporin, 15-30 minutes prior to emergency cholecystectomy

- No antibiotic prophylaxis

Contacts

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Eligibility criteria

Inclusion criteria

- Mild or moderate acute calculous cholecystitis

- Cholecystectomy

- Written informed consent

Exclusion criteria

- < 18 years of age

- Acalculous cholecystitis

- Severe acute calculous cholecystitis

- Already receiving antibiotics prior to inclusion

- Proven allergy to cefazoline

- Pregnancy

- Indication for ERCP on admission

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):	01-03-2016
Enrollment:	454
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43999
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5667
NTR-old	NTR5802
CCMO	NL53084.100.15
OMON	NL-OMON43999

Study results

Summary results

NA