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

No registrations found.

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

Summary

ID

NL-OMON27470

Source
NTR

Brief title
PEANUTS

Health condition

Acute calculous cholecystitis
(Dutch: Acute calculeuze cholecystitis)

Sponsors and support

Primary sponsor: St. Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

All infectious complications.

Secondary outcome

1. Individual components of composite endpoint;

2. All other complications;

3. Total length of hospital stay;

4. Total direct and indirect costs.

Study description

Background summary

In the treatment of acute cholecystitis the use of antibiotics is disputable. It is current practice to administer a single prophylactic dose of intravenous antibiotics 15-30 minutes prior to the first incision. Whether postoperative prolongation of antibiotic treatment has any additional value in preventing infectious complications remains unclear but many surgeons still advise to do so. Since the agents are preferably administered through the intravenous route, hospital admission is lengthened and therefore costs are higher. In addition bacterial resistance can occur making future treatment more difficult.

Current literature and our own retrospective case series does not provide the surgical community with the much needed answer to the question whether prolonged postoperative antibiotic prophylaxis does decrease the infectious complication rate in low risk patients with acute cholecystitis.

Although selection bias is most certainly present in the available studies, results do not show any beneficial effect of prolonged antibiotic administration.

The PEANUTS trial is initiated to demonstrate that extended postoperative antibiotic therapy does not decrease the infectious complication rate in laparoscopic cholecystectomy for acute cholecystitis. It is designed as a multi centre randomized controlled trial, including low risk patients with acute calculous cholecystitis. Patients will be randomised to receive either extended postoperative antibiotic prophylaxis or clinical observation after laparoscopic cholecystectomy. The endpoint is a composed endpoint of all infectious complications.

Study objective

Extended postoperative antibiotic prophylaxis will not reduce the infectious complication rate after laparoscopic cholecystectomy in acute cholecystitis.

Study design

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

An interim analysis will be performed every six months.

Intervention

1. Extended postoperative antibiotic prophylaxis (cefuroxime 750 mgs 3dd & metronidazole 500mgs 3dd during 72 hours);

2. Postoperative clinical observation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Acute calculous cholecystitis;

2. APACHE-II score 1-6;

3. Written informed consent.

Exclusion criteria

1. < 18 years of age;

2. APACHE-II score ≥ 7;

3. Already receiving antibiotics prior to diagnosis;

4. Proven allergy to Cefuroxime/ Metronidazole;

5. Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	158
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-09-2011
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	NL2942
NTR-old	NTR3089
Other	VCMO Antonius Hospital Nieuwegein :
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A