Perioperative antibiotic use in the treatment of acute calculous cholecystitis

Published: 03-11-2011
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To demonstrate that extended postoperative antibiotic treatment does not decrease the infectious complication rate in laparoscopic cholecystectomy for acute cholecystitis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gallbladder disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39145

Source
ToetsingOnline

Brief title
PEANUTS Trial

Condition

- Gallbladder disorders

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 financiele ondersteuning voor dit onderzoek.

Intervention

Keyword: Acute cholecystitis, Antibiotics, Infection, Laparoscopic cholecystectomy

Outcome measures

Primary outcome

Composite endpoint consisting of all infectious complications:

- Wound infection

- Intra-abdominal infection

- Pneumonia

- Urinary tract infection

Secondary outcome

- All individual components of the composite endpoint

- Other complications

- Need for re-intervention

- Need for re-admission

- Total duration of admission

- 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 treatment.

Study objective

To demonstrate that extended postoperative antibiotic treatment does not decrease the infectious complication rate in laparoscopic cholecystectomy for acute cholecystitis.

Study design

Multi center randomized controlled open trial

Intervention

Extended postoperative antibiotic prophylaxis (cefuroxime 750mgs 3dd/ metronidazole 500mgs 3dd) intravenously during 72 hours

Study burden and risks

There are na additional risks associated with participation in this trial. Both intervention methods (extended postoperative antibiotic prophylaxis and clinical observation) are used widely in the current surgical community. The risks of participation are therefore no greater or different from those associated with treatment according to the local hospital protocol.

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

* Acute calculous cholecystitis, defined according to Tokyo Guidelines
* Laparoscopic cholecystectomy
* APACHE-II score 1-6

Exclusion criteria

* < 18 years of age
* APACHE-II score >= 7
* Already receiving antibiotics at time of/prior to diagnosis
* Proven allergy to cefuroxime/ metronidazole
* Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2012
Enrollment:	158
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cefuroxime
Generic name:	Cefuroxime
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Metronidazole
Generic name:	Metronidazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	26-02-2013
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:	23-07-2013
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	ID
EudraCT	EUCTR2011-004878-29-NL
CCMO	NL38015.100.11