The use of perioperative antibiotic prophylaxis in the treatment of acute cholecystitis, a randomized, multicenter, non-inferiority trial

Published: 24-11-2015
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To provide high level of evidence that omitting perioperative antibiotic prophylaxis does not increase the postoperative infection rate, in patients with acute calculous cholecystitis undergoing laparoscopic cholecystectomy.

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

Summary

ID

NL-OMON43999

Source
ToetsingOnline

Brief title
PEANUTS 2

Condition

- Gallbladder disorders

Synonym
cholecystitis, inflamed gallbladder

Research involving
Human

Sponsors and support

Primary sponsor: Antonius Ziekenhuis Nieuwegein

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute calculous cholecystitis, Antibiotic prophylaxis, Gastrointestinal surgery, Laparoscopic cholecystectomy, Postoperative infection

Outcome measures

Primary outcome

The primary outcome measure is the development of postoperative infections

(surgical site and distant infections) within 30 days after surgery.

Secondary outcome

Secondary endpoints are the individual postoperative infections, other

postoperative complications, duration of hospital stay and total costs.

Study description

Background summary

Acute calculous cholecystitis is the third most frequent cause of emergency admissions to surgical wards. The standard treatment is cholecystectomy. It is current practice to administer a single prophylactic dose of intravenous antibiotics, prior the incision.

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. Besides, different studies suggest that extended antibiotic prophylaxis provides no benefit in preventing postoperative infections in patients with acute cholecystitis undergoing emergency cholecystectomies.

The remaining quenstion is whether even a single dose of antibiotic prophylaxis, current practice, is beneficial in case of emergency cholecystectomy for acute calculous cholecystitis. We hypothesize that omitting antibiotic prophylaxis in these patiënts does not lead to an increase in postoperative infection rate

If this study demonstrates that the absence of antibiotic prophylaxis does not

increase the infection rate, the use of perioperative antibiotic for this indication can be dropped as a whole and the guidelines will be adapted. When the use of antibiotics appears unnecessary in these patients, the role of antibiotic prophylaxis in the entire upper gastrointestinal tract surgery becomes eminent. A decrease of use of antibiotics on such a scale may result in a large decrease of needless medical activities, costs and bacterial resistance.

Study objective

To provide high level of evidence that omitting perioperative antibiotic prophylaxis does not increase the postoperative infection rate, in patients with acute calculous cholecystitis undergoing laparoscopic cholecystectomy.

Study design

A randomized controlled, multicenter, non-inferiority trial.
Patients will be randomly allocated to:
* No antibiotic treatment
* A single dose of 2000 milligrams of first generation cephalosporin (20mL), 15-30 minutes prior to surgery.

Intervention

Omitting antibiotic prophylaxis

Study burden and risks

If this study demonstrates that omitting antibiotic prophylaxis does not increase the infection rate, it*s use for this indication can be dropped as a whole and the guidelines will be adapted. Then, the role of antibiotic prophylaxis in the entire upper gastrointestinal tract surgery becomes eminent. A decrease of use of antibiotics on such a scale may result in a large decrease of needless medical activities, costs and bacterial resistance.
If omitting antibiotic prophylaxis should be unjust, an infection that could have been prevented by antibiotic prophylaxis may occur. A distant infection requires antibiotic treatment, a surgical site infection may require opening of the wound or percutaneous drainage of an intra-abdominal abscess. All procedures in this study are part of the normal medical treatment for acute cholecystitis, no extra (invasive) procedures or laboratory tests will be performed. Patient will be seen at the outpatient clinic one week postoperative and will be called to answer questions, four weeks after surgery.

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 as mild or moderate according to Tokyo Guidelines
* Cholecystectomy
* Written informed consent

Exclusion criteria

* < 18 years of age
* Acalculous cholecystitis
* Acute calculous cholecystitis, defined as severe according to Tokyo Guidelines
* Patients who received antibiotic treatment on admission
* Proven allergy to cefazolin

* Pregnancy
* Immune compromised patients
* Indication for endoscopic retrograde pancreaticocholangiography (ERCP) on admission

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	454
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	24-11-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-06-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-05-2018
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

ID: 24030
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-001536-38-NL
CCMO	NL53084.100.15
OMON	NL-OMON24030