

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gallbladder disorders
<b>Study type</b>	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 question 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 patients 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, its 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

### Public

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### Scientific

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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 pancreaticholangiography (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: Nationaal Trial Register

Title:

## In other registers

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