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

Gepubliceerd: 31-05-2016 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24030

Bron
NTR

Verkorte titel
PEANUTS II

Aandoening

Acute calculous cholecystitis

Ondersteuning

Primaire sponsor: St. Antonius Hospital
Overige ondersteuning: St. Antonius Research Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is a composite endpoint consisting of all postoperative infectious

complications occurring during the first 30 days after surgery

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

- No antibiotic prophylaxis

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Mild or moderate acute calculous cholecystitis

- Cholecystectomy

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- < 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	454
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43999
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

NA