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

Gepubliceerd: 29-09-2011 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON27470

Bron
NTR

Verkorte titel
PEANUTS

Aandoening

Acute calculous cholecystitis
(Dutch: Acute calculeuze cholecystitis)

Ondersteuning

Primaire sponsor: St. Antonius Hospital, Nieuwegein
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

All infectious complications.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

1. Extended postoperative antibiotic prophylaxis (cefuroxime 750 mgs 3dd & metronidazole

500mgs 3dd during 72 hours);

2. Postoperative clinical observation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Acute calculous cholecystitis;

2. APACHE-II score 1-6;

3. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	158
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2942
NTR-old	NTR3089
Ander register	VCMO Antonius Hospital Nieuwegein :
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A