Short versus standard course postoperative antibiotic treatment for complex acute appendicitis

Gepubliceerd: 20-12-2016 Laatst bijgewerkt: 15-05-2024

We hypothesize that discontinuing postoperative antibiotic treatment after 2 days is non-inferior to 5 days of antibiotic treatment.

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

Samenvatting

ID

NL-OMON24288

Bron
Nationaal Trial Register

Verkorte titel
APPIC (Antibiotics following aPPendectomy In Complex appendicitis)

Aandoening

Complex acute appendicitis

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is a composite endpoint postoperative infectious complications related

to appendectomy, including intra-abdominal abscess and surgical site infection, and mortality within 90 days after appendectomy.

Toelichting onderzoek

Achtergrond van het onderzoek

Currently there is no consensus on the adequate duration of postoperative antibiotic treatment following appendectomy in complex appendicitis, due to a lack of medical evidence. Furthermore antibiotic resistance is a growing global health issue. The present study will investigate whether a short course (2 days) is as safe and effective as standard practice (5 days). The hypothesis is that short course is non-inferior to standard course. If this is proven, potential benefits of this study are less use of antibiotics, less overtreatment and resistance, as well as possibly shorter length of stay and lower hospital costs for this patient group.

Principal Investigators: A.L. van den Boom (Erasmus MC; UMC Groningen) and B.P.L. Wijnhoven (Erasmus MC)

Doel van het onderzoek

We hypothesize that discontinuing postoperative antibiotic treatment after 2 days is non-inferior to 5 days of antibiotic treatment.

Onderzoeksopzet

90 days (for all outcomes)

Onderzoeksproduct en/of interventie

After appendectomy for complex acute appendicitis, patients will be randomized to either A) discontinuing antibiotic treatment after 48 hours of intravenous antibiotics (intervention group), or B) continuing antibiotic treatment for three more days (control group). Antibiotics given intravenously are cefuroxime and metronidazole. In children the doses will be adjusted according to their weight.

Contactpersonen

Publiek

Erasmus MC Rotterdam, suite Na-2117
E.M.L. de Wijkerslooth
s Gravendijkwal 230

Rotterdam 3015CE
The Netherlands
+31617616440

Wetenschappelijk

Erasmus MC Rotterdam, suite Na-2117
E.M.L. de Wijkerslooth
s Gravendijkwal 230

Rotterdam 3015CE
The Netherlands
+31617616440

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- age minimum 8 years old (no upper limit)

- patients with suspected acute appendicitis, awaiting appendectomy

- written informed consent

- intraoperative diagnosis of a complex appendicitis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- not able to give informed consent

- appendectomy à froid

- severe sepsis, defined as sepsis-induced tissue hypoperfusion or organ dysfunction

- conservative treatment of acute appendicitis

- ASA score IV or not able to undergo surgery

- known allergy or any other contraindication for the use of the study medication

- immunocompromised patients

- pregnancy

- use of other antibiotics

- intraoperative diagnosis of a simple appendicitis

- intraoperative appendicular infiltration not amendable for appendectomy

- inadequate source control in the opinion of the surgeon

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-04-2017
Aantal proefpersonen:	1066
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-12-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45262
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5946
NTR-old	NTR6128
CCMO	NL59492.078.16
OMON	NL-OMON45262

Resultaten