# Short versus standard course postoperative antibiotic treatment for complex acute appendicitis

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24288

**Source**
Nationaal Trial Register

**Brief title**
APPIC (Antibiotics following aPPendectomy In Complex appendicitis)

**Health condition**

Complex acute appendicitis

### Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Rotterdam
**Source(s) of monetary or material Support:** ZonMw

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

Secondary objectives are cost-effectiveness, intra-abdominal abscess, superficial and/or deep surgical site infections, mortality, duration of postoperative antibiotic treatment, re-start of antibiotics, hospital stay in hours from the operation, time to reach discharge criteria in hours from the operation, emergency room visits, readmission rate and adverse events on antibiotics (all within 90 days after appendectomy).

## Study description

### Background summary

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)

### Study objective

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

### Study design

90 days (for all outcomes)

### Intervention

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

- age minimum 8 years old (no upper limit)

- patients with suspected acute appendicitis, awaiting appendectomy

- written informed consent

- intraoperative diagnosis of a complex appendicitis

## Exclusion criteria

- 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

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-04-2017 |
| Enrollment: | 1066 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion
Date: 20-12-2016
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 45262
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

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

# Study results