Antibiotic treatment alone for children with acute appendicitis; a prospective cohort study part of the Antibiotic versus Primary Appendectomy for Children with acute appendicitis; the APAC trial.

Published: 18-05-2012
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1. What is the complication rate of the initial antibiotic treatment strategy for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Interventional

Summary

ID

NL-OMON39690

Source
ToetsingOnline

Brief title
Antibiotic treatment alone for acute simple appendicitis in children

Condition

- Gastrointestinal infections

Synonym
Appendicitis, inflamed appendix

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute appendicitis, Antibiotic treatment, Simple appendicitis

Outcome measures

Primary outcome

Safety of antibiotic treatment defined as:

Occurrence of major complications:

a. Anaphylactic shock and other allergic reaction to antibiotics administered.

b. Recurrent appendicitis within 8 weeks

c. Recurrent appendicitis within one year after discharge

d. Development of perforated appendicitis

e. Occurrence of major complaints after delayed appendectomy such as

Intra-abdominal abscess, stump leakage, secondary bowel obstruction,

superficial site infection, need for secondary operation, need for

re-intervention other than appendectomy, re-admission, anaesthesia related

complications, pneumonia.

f. Re-admission

g. Re-intervention other than delayed appendectomy

Secondary outcome

Secondary research question:

What is the complication rate of the direct appendectomy treatment strategy for

acute simple appendicitis (radiological proven) in children aged 7-17 years

old? .

Additional research questions:

1. What is the quality of life of patients and family treated with antibiotic treatment alone?

2. What is the quality of life of parents and family treated with appendectomy?

2. What is the current opinion about acute appendicitis in both the medical society as well as the general public?

3. Is failure of antibiotic treatment alone for simple appendicitis predictable by certain clinical, laboratory parameters or radiological features?

4. What are the changes on ultrasonography of the appendix after two days of intravenous antibiotics?

5. Is ultrasonography useful in predicting failure of antibiotic treatment alone?

6. Can we identify risk factors of developing recurrent appendicitis within one year?

Study description

Background summary

Appendectomy for acute appendicitis has recently been questioned as being the only correct treatment for appendicitis. Appendectomy has been reported to have significant early and late morbidity. This can be avoided with antibiotic treatment alone. Moreover, better quality of life and lower costs have been associated with antibiotic treatment alone. Five clinical trials in selected patients (males, older than 18 years) comparing appendectomy and antibiotic

treatment alone as primary mode of treatment found that antibiotic treatment alone is safe and effective in more than 48-95% of the patients Conclusive evidence with regard to the efficacy of antibiotic treatment alone in children with proven acute appendicitis however is lacking. We propose a prospective cohort study to answer the following questions

Study objective

1. What is the complication rate of the initial antibiotic treatment strategy for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Study design

Prospective multi-center cohort study.

Intervention

Intravenous administration of amoxicillin/clavulanic acid 25/2.5mg 6-hourly (total 100/10 mg/kg daily) and gentamicin 7mg/kg once daily will be given for 48 hours. If possible the antibiotics will be switched to oral amoxicillin/clavulanic acid 50/12.5 mg/kg 8-hourly for in total 7 days

Patients will be admitted at least for 48 hours

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
1. Risks of participation: Need for 'secondary' operation, recurrent appendicitis, risk of perforation. Risks that are also present in case of non-participation: Allergic reaction to antibiotics, appendectomy associated complications
2. Burden of participation: Admission of at least 2 days (compared to 1-2 days with appendectomy), ultrasonography after 24 hours (extra procedure), outpatient follow up (two extra procedure), filling out QOL questionnaires (3x). Burden also present in case of non-participation: Intravenous access (normal procedure), daily blood samples (normal procedure),
3. Benefit of participation: Avoidance of surgery and its related early and late morbidity, potential better quality of life.

Burden of control group:
1. One extra out patient visit after 8 weeks
2. Filling out QOL questionnaires (3x)
3. Telephone follow up after one year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Written Informed consent obtained
* Age 7-17 years
* Radiologically confirmed simple appendicitis, defined as:
a. Clinical findings:
i. Unwell, but not generally ill
ii. Localized tenderness in the right iliac fossa region
iii. Normal/hyperactive bowel sounds
iv. No guarding
v. No mass palpable
b. Ultrasonography:
i. Incompressible appendix with an outer diameter of *6 mm

ii. Hyperaemia within the appendiceal wall
iii. With or without faecolith
iv. Infiltration of surrounding fat
v. No signs of perforation
vi. No signs of intra abdominal abscess/phlegmone

Exclusion criteria

The following patients will be excluded from participating in this study:
1. Patients with severe general illness at time of presentation:
a. Generalized peritonitis defined as:
Diffuse inflammation of the peritoneum with clinical signs consisting of increasing abdominal pain, generalized tenderness, diffuse abdominal rigidity, sinus tachycardia, signs of paralytic ileus
b. Severe sepsis or septic shock, as defined by the international paediatric sepsis consensus conference [36]. See attachment 1.
c. Signs of complex appendicitis;2. Patients with serious associated conditions or malformations such as:
a. Congenital or acquired cardiac or pulmonary disease with significant hemodynamic consequences
b. Immunodeficiency
c. Malignancy
d. Homozygous sickle cell disease
e. Metabolic disorders;3. Patient with documented type 1 allergy to the antibiotics used;4. Children with faecolith on ultrasound

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2012
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Augmentin
Generic name:	Amoxicillin/clavulanic acid
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Gentamicin
Generic name:	Gentamicin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-004495-12-NL
ClinicalTrials.gov	NCT01356641
CCMO	NL38141.029.11

Study results

Date completed:	12-01-2017
Results posted:	19-02-2018
Actual enrolment:	50

First publication
08-12-2017