Antibiotica voor de behandeling van acute blindedarmontsteking bij kinderen.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26391

Source
NTR

Health condition

Appendicitis
children
Antibiotic treatment
Non-operative treatment

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

Safety of initial antibiotic treatment defined as:

Occurrence of major complications, such as:

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 (IAA), stumpleakage, superficial site infection (SSI), anaesthesia related complications, secondary bowel obstruction (SBO), re-admission, need for re-intervention

f. Re-admission

g. Re-intervention other than delayed appendectomy

Secondary outcome

Major complications associated with appendectomy

a. Stumpleakage

b. Intra-abdominal abscess (IAA)

c. Secondary bowel obstruction (SBO)

d. Superficial site infection (SSI)

e. Need for secondary operation

f. Need for other re-intervention

g. Re-admission

h. Anaesthesia related complication

i. Pneumonia

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 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:

Primary research question:
What is the complication rate of the initial antibiotic treatment strategy (IATS) for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Secondary research question:
What is the complication rate of the direct appendectomy treatment strategy (DATS) for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Study objective

N/A

Study design

1. Short term (1 month);

2. Long term (1 year).

A QOLquestionaire will be used for measurements.

Intervention

Initial antibiotic treatment strategy (IATS): Intravenous administration of amoxicillin/clavulanic acid 25/2.5mg 6-hourly (total 100/10 mg/kg daily; maximum 6000/600mg a day) 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 (max 1500/375mg a day) for in total 7 days. If after 72 hours, the patient does not meet the predefined criteria, an appendectomy will be performed.

Contacts

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Eligibility criteria

Inclusion criteria

• 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 (see appendix 13.13):

i. Incompressible appendix with an outer diameter of ≥6 mm

ii. Hyperaemia within the appendiceal wall

iii. Without faecolith

iv. Infiltration of surrounding fat

v. No signs of perforation

vi. No signs of intra-abdominal abscess/phlegmone

Exclusion criteria

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 [38]. (appendix 13.6)

c. Signs of complex appendicitis

2. Children with a faecolith on ultrasonography.

3. 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2681
NTR-old	NTR2810
Other	Kinderchirurgisch Centrum Amsterdam : KCA2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A