Initial non-operative treatment versus direct operative treatment for simple appendicitis in children.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26428

Source
NTR

Brief title
APAC study

Health condition

Appendicitis

Sponsors and support

Primary sponsor: Academisch medisch centrum Amsterdam
Source(s) of monetary or material Support: This study is funded by ZONmw

Intervention

Outcome measures

Primary outcome

The primary outcome is the proportion of patients experiencing complications within one month follow-up. An adjudication committee will be installed to review the complications. They will review all patients with possible complications to determine

whether or not they fulfill the criteria for complications. All Complications will be recorded.

Complications are defined as:

• Allergic reaction to antibiotics administered. In case an allergic reaction is suspected, the child will be referred to the allergist for further evaluation.

• Re-admission for an indication other than recurrent appendicitis but related to appendicitis (such as readmission for observation of fever or abdominal pain)

• Complications associated with appendectomy:

- Superficial Site infection

- Intra-abdominal abscess

- Stump leakage/stump appendicitis

- Secondary / prolonged Bowel Obstruction

- Anesthesia Related complications (such us pneumonia)

- Hernia cicatricalis

- Need for other surgical or radiological intervention than appendectomy but related to appendicitis (such as percutaneous drainage of an abscess, surgical intervention for a superficial site infection)

Secondary outcome

Secondary objectives consist of:

- Proportion of patients experiencing early failure in the initial nonoperative treatment group (time: 7 days)

- Pain score measured by the Visual Analogue Scale (time: during clinical phase)

- Pain medication used (time 7 days)

- Proportion of patients with missed diagnosis of complex appendicitis (one month)

At one, 6 and 12 months

- Number of days absent from work/school

- Number of extra visits to the ER/outpatient clinic/GP

- Total number of in-hospital days

- Proportion of patients not having to undergo an appendectomy

- Proportion of patients experiencing recurrent appendicitis

- HR-QOL (CHQ-87, EQ-5d-Y, EQ-5d-Proxy)

- Direct and indirect medical and non-medical costs

- Patients satisfaction (PSQ-18, NPS)

- Factors influencing implementability

Study description

Study objective

Initial non-operative treatment strategy is associated with as many or fewer complications, a better health-related QOL, reduced
costs, and it avoids surgery in the majority of patients.

Study design

Outcomes will be measured at discharge, 7 days, 1, 6, and 12 months after randomization as described above.

Intervention

Intervention group (Non-operative treatment strategy): Clinical observation for 48 hours with administration of 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 for 48 hours. If after 48 hours the patient fulfils the predefined discharge criteria, 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 and discharge. An appendectomy is reserved for those patients with clinical deterioration, non-improvement after 72 hours or recurrent appendicitis.

Control group (Operative treatment strategy): Clinical observation and semi-urgent appendectomy. Pre-, peri- and postoperative care according to local protocol. No routine postoperative antibiotics. Discharge if the patient fulfils the predefined discharge criteria.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria:

Eligible for inclusion are all children from 7 to 17 years old, inclusive, with a radiologically confirmed simple appendicitis.

Definition of simple appendicitis is based upon predefined clinical, biochemical and radiological (ultrasound) criteria.
Clinical & biochemical criteria:

- Unwell but not generally ill

- Localized tenderness in the right iliac fossa region

- Normal/hyperactive bowel sounds

- No guarding or palpable mass

- Biochemical signs of infection (Elevated White Blood Cell count (WBC) and/or C-reactive protein (CRP)).

As recommended by the national guideline, all children with a clinical and/or biochemical suspicion should undergo ultrasound
studies. Ultrasound criteria to confirm the diagnosis of acute simple appendicitis are:

- An incompressible, painful appendix with an outer diameter > 6 mm

- Secondary signs of inflammation such as surrounding fat infiltration, limited clear free fluid surrounding the appendix,
hyperemia within the appendiceal wall.

- No fecolith, no signs of perforation, no signs of intra-abdominal abscess or phlegmone.

In case the ultrasound is inconclusive, additional imaging studies may be obtained. CT-scan is not recommended in the young children (due to its risk of radiation induced malignancy). MRI is recommended in those places with sufficient experience in the interpretation of the results. Only those in whom imaging studies confirm the diagnosis of simple appendicitis can be included.

In case there is no certain diagnosis and a “watchful waiting” strategy is chosen, the patient cannot be included.

Exclusion criteria

• Generalized peritonitis, complex appendicitis or sepsis (based upon predefined criteria and scoring system).

Scoring system: A scoring system was developed determining the risk of complex appendicitis based upon five pre-operative variables. Points have been awarded to each variable. In case the total score is less than 4 points, the patient is likely to have a simple appendicitis. In case the score is 4 or more points, the chance of having complex appendicitis is
significant and those children will be excluded from this study.
Variables:

Diffuse abdominal guarding (3 points)

CRP level more than 38 mg/L (2 points)

Signs on ultrasound indicative of complex appendicitis (2 points)

More than one day abdominal pain (2 points)

Temperature: more than 37.5 degree Celsius (1 point)

• Fecolith (ultrasound)

• Serious co-morbidity

• Recurrent appendicitis

• Suspicion of an underlying malignancy or inflammatory bowel disease

• Documented type 1 allergy to the antibiotics used.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2016
Enrollment:	334
Type:	Anticipated

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	NL5822
NTR-old	NTR5977
Other	: APAC2016

Study results