The optimal treatment strategy for complex appendicitis in the pediatric population

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Subgroup 1 (complex appendicitis without mass and/or abscess formation): LA is associated with reduced superficial site infections, shorter length of stay, less costs, less pain, and better hr-QoL, compared with OA without compromising overall…

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Observational non invasive

Summary

ID

NL-OMON26201

Source
Nationaal Trial Register

Brief title
CAPP study

Condition

- Gastrointestinal infections

Health condition

Acute complex appendicitis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Secondary sponsors:	ZonMw
Source(s) of monetary or material Support:	ZonMw (Leading the Change)

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The proportion of patients experiencing any complication within 3 months after inclusion. All complications / events will be recorded and scored according to the Clavien-Dindo scale. The following events will be considered as complications but this list is not exhaustive: - Superficial Site infection: Criteria according to the CDC guidelines - Intra-abdominal abscess: Radiologically confirmed fluid collection containing pus or infected material that is surrounded by inflamed tissue. - Stump leakage / stump appendicitis: Radiologically confirmed intra-abdominal fluid collections after appendectomy / recurrence of disease after appendectomy. - Secondary / Prolonged bowel obstruction (including paralytic ileus): Patient requiring gastro-intestinal decompression with a nasogastric tube. - Anesthesia related complications (such as pneumonia) - Operation / trocar site hernia: Clinically confirmed by a resident or surgeon. - Need for additional surgical or radiological interventions related to primary disease (appendicitis) - Recurrent appendicitis: recurrence of disease within 3 months time after inclusion. - Re-admission for an indication related to appendicitis (such as readmissions for observation of fever and abdominal pain) All complications and their subsequent treatment will be registered.

Secondary outcome

- Proportion of patients experiencing overall complications during admission (patient-level) - Proportion of patients experiencing overall complications within 30 days (patient-level) - Proportion of patients with a PAA within 3 months after inclusion (patient-level) - Proportion of patients with an SSI within 3 months after inclusion (patient-level) - Proportion of patients with a secondary/prolonged bowel obstruction within 3 months after inclusion (patient-level) - Number of days absent from school, social or sport events within 3 months after inclusion (patient-level) - Number of days absent from work within 3 months after inclusion (parents-level) - Total number of extra visits (not the already scheduled ones) to the outpatient clinic, general practitioner’s office or emergency department for abdominal pain within 3 months after inclusion. - Total length of hospital stay during follow-up period for strategy related treatment or complications. - Level of pain during admission (measured by the validated Visual Analogue Scale) - Pain medication utilization during admission - Proportion of patients not having to undergo appendectomy within 3 months after inclusion (subgroup 2 specifically) - Proportion of patients experiencing recurrent appendicitis within 3 months after

inclusion. (subgroup 2 specifically) - Recurrent appendicitis is defined as those patients with a clinical and radiological high suspicion of recurrent appendicitis who undergo an appendectomy and histopathological examination confirms the diagnosis of recurrent appendicitis - Proportion of patients experiencing early failure of initial non-operative treatment. (subgroup 2 specifically) Early failure is defined as all patients that undergo an appendectomy during the antibiotic course (iv or oral) due to persistent complaints, clinical deterioration or faecolith. - Proportion of patients that undergo interval appendectomy within 3 months after inclusion. (subgroup 2 specifically) Interval appendectomy is defined as those patients that undergo an appendectomy with a clinical and radiological low suspicion of recurrent appendicitis. Histopathological examination shows no signs of recurrent appendicitis. - QoL measured by the validated EQ-5d-Youth, EQ-5d-Proxy questionnaire and PedsQL 4.0 at admission, 30 days after inclusion, 3 months after inclusion - Medical, non-medical and indirect costs until 3 months after inclusion of the treatment strategy measured by the Health and Labor Questionnaire (HLQ), Medical Consumption Questionnaire (iMCQ) and Productivity Consumption Questionnaire (iPCQ) and gathered actual health care cost - Patient satisfaction measured by the NET PROMOTOR SCORE and validated Patient Satisfaction Questionnaire (PSQ) at 3 months after inclusion.

Study description

Background summary

This is a nation-wide, multi-center, comparative, prospective cohort study with standardized treatments. Aim of this study is to evaluate the effect of different treatment strategies on overall complications, health related-Quality of Life (hr-QOL) and costs among two subtypes of complex appendicitis in children (<18 years old). Main research questions: What is the difference in overall complications at three months between: Subgroup 1 (complex appendicitis without abscess/mass formation): Laparoscopic (LA) and open appendectomy (OA) Subgroup 2: (complex appendicitis with abscess/mass formation): Non-operative treatment (NOT) and direct appendectomy

Study objective

Subgroup 1 (complex appendicitis without mass and/or abscess formation): LA is associated with reduced superficial site infections, shorter length of stay, less costs, less pain, and better hr-QoL, compared with OA without compromising overall complications. Subgroup 2 (complex appendicitis with mass and/or abscess formation): NOT is associated with reduced overall complications, shorter length of stay, better hr-QoL compared with direct appendectomy.

Study design

Outcomes will be measured at the day of inclusion (= day 0), 3 days, 5 days, at discharge, 30 days, and 3 months after inclusion.

Intervention

Interventions: Subgroup 1: Laparoscopic appendectomy Subgroup 2: Non-operative treatment (consisting of intravenous antibiotics with or without (percutaneous) drainage procedure) Usual care/comparison (controls) Subgroup 1: Open appendectomy Subgroup 2: Direct appendectomy

Contacts

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Eligibility criteria

Age
Adolescents (16-17 years)
Adolescents (16-17 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Children (2-11 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Eligible for inclusion are all children <18 years old that need to undergo treatment for the suspicion of complex appendicitis. Suspicion of complex appendicitis is based upon the following predefined criteria: - 4 or more points on our scoring system developed to predict complex appendicitis. This scoring system consists of five variables (clinical, biochemical and radiological, each awarded points). In case the total score is 4 or more points, the patient is

likely to have complex appendicitis. Variables included in the scoring system are: - Diffuse abdominal guarding (3 points) - CRP level more than 38 mg/L (2 points) - Signs on ultrasound / imaging indicative for complex appendicitis (2 points) - More than one day abdominal pain (2 points) - Temperature more than 37.5 degrees Celsius (1 point) Or - High index of suspicion of complex appendicitis by the treating physician. If this is the case, the treating physician will make pre-treatment note upon what clinical, biochemical or radiological variable the high index of suspicion is based. Classification into the two subgroups of complex appendicitis will be based upon clinical and radiological features. If signs suggestive of perforated appendicitis AND intra-abdominal abscesses or enlarged mass formation are present, patients will be categorized as subgroup 2. If no abscess or enlarged mass is present on clinical exam and/or additional imaging, patients will be categorized as subgroup 1.

Exclusion criteria

1. Adult patients (=18 years old) 2. Children with a suspicion of simple appendicitis (based upon the previous mentioned scoring system and radiological features)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2019
Enrollment:	1308
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	NL9371
Other	METC AMC : W18 302 # 18.348

Study results