Differentiating simple from complex appendicitis in children before surgery: The Complex Appendicitis Tool (CAT)

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1. Immunology and Pathology:To determine the immune response of patients with simple and complex appendicitis in order to identify markers which distinguish between simple and complex appendicitis.2.Clinical and Imaging:To analyze the differences in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON43987

Source
ToetsingOnline

Brief title
Preoperative discrimination between simple and complex appendicitis

Condition

- Gastrointestinal infections
- Bacterial infectious disorders
- Gastrointestinal therapeutic procedures

Synonym
Complex appendicitis, Simple appendicitis

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: Complex appendicitis, Immunology, Simple appendicitis

Outcome measures

Primary outcome

Type of appendicitis, gender, age, symptoms at time of presentation, duration of abdominal pain, fever, heart rate, laboratory results at the time of diagnosis, findings on radiological imaging. Per operative findings and conclusion.

Immunology: levels of cytokines, kind of leucocytes in peripheral blood samples.

Histopathology: number and kind of immune cells in the appendix. Cellular staining by flowcytometry

Bacteriology: Microbiome

Secondary outcome

nvt

Study description

Background summary

It appears that there are two types of appendicitis: simple appendicitis (not perforating) and complex appendicitis (perforating). Current literature suggests that treatment strategies of the two types should be different. Therefore correct preoperative diagnosis is crucial to optimize the treatment

of patients with appendicitis. The exact pathogenesis of each type remains unclear, but there is evidence that the immune system may play a crucial role. The aim of this study is twofold. First we want to investigate the immune response of patients with both simple and complex appendicitis. Second, this study aims to develop an instrument usable in the emergency room to distinguish simple from complex appendicitis

Study objective

1. Immunology and Pathology:
To determine the immune response of patients with simple and complex appendicitis in order to identify markers which distinguish between simple and complex appendicitis.

2.Clinical and Imaging:
To analyze the differences in symptoms, laboratory results and ultrasound features of both simple and complex appendicitis in children with histological proven appendicitis in both university and general hospital setting

To develop an instrument usable in the emergency department to distinguish simple from complex appendicitis preoperatively

To prospectively validate this instrument in a cohort of patients

Study design

Prospective multi centre cohort study.

Study burden and risks

Burden: Common practise is to take a blood sample from the patient with suspected appendicitis to evaluate the levels of C-reactive protein and leucocytes (and differentiation). For our study an extra amount of blood (1.5ml; heparin tube) will be taken and frozen for analysis of the cytokines profile. In addition the rest of the study will not lead to an extra burden.
The patient will be diagnosed and treated for their suspected appendicitis as normal (i.e. blood sample and imaging studies and appendectomy). After our primary analysis of differences between simple and complex appendicitis a tool will be made. Prior to surgery, the admitting surgeon should note if based on our tool the patient has a simple or complex appendicitis. The intraoperative diagnosis will afterwards be checked. Rectal swab during general anaesthesia is considered a low burden. It is normal to remove the appendix during appendectomy and sent it for histopathologic examination. We will now take 1 cm from the tip for bacteriologic and immunologic analysis.

Risks: There is a small chance that blood will be taken, but we will not analyse this blood sample in this study. Blood will be stored and may be used for further studies. Smaal chance of missing carcinoid.

Benefit:
Individual: none
Group: The benefit of this study will be that patients can be diagnosed correctly preoperatively with either simple or complex appendicitis and that treatment strategies can be optimized based on their diagnosis.

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

3.1 Population (base)
All children 0-17 presenting at the ER department in one of the three hospitals with the suspicion of an acute appendicitis are eligible for inclusion.;3.2 Inclusion criteria (in the simple or complex appendicitis group)
All children 0-17 presenting at the ER department in one of the three hospitals with the suspicion of an acute appendicitis are eligible for inclusion.;3.3 Control group
Children presenting at the ER with abdominal pain with the suspicion of acute appendicitis, although non-infectional cause or no cause was found however.

Exclusion criteria

Age older than 17 years old
Appendicular infiltrate
Appendectomy a froid
Appendix Sana
Malignancy of the appendix
Non-operative management
Abdominal pain caused by other infectious disease such as lymphadenitis mesenteric, pneumonia etcetera.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-04-2016

Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2016
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
CCMO	NL51312.029.14