Association between viral and bacterial infections and the pathogenesis of acute appendicitis in children

Published: 26-09-2016 Last updated: 16-04-2024

The objective is to investigate the correlation between bacterial/viral gut infections and acute appendicitis in children.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON43102

Source ToetsingOnline

Brief title Association infections and appendicitis in children

Condition

• Gastrointestinal inflammatory conditions

Synonym Appendicitis, inflammation of the appendix

Research involving Human

Sponsors and support

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

Intervention

Keyword: Appendicitis, Bacteria, Viruses

Outcome measures

Primary outcome

The main study parameters are the bacteria and viruses present, and their mutual frequence ratio, in the wall of the resected inflamed appendix together with the presence of these bacteria and gastrointestinal viruses in feces and the viruses in the blood samples.

Secondary outcome

Other parameters that will be analyzed are patient factors like diagnosis

(perforated or non-perforated appendicitis), age and gender. Furthermore,

information on possible confounding factors, such as use of antibiotics or

other medicine, use of probiotics, and diet, will be collected.

Study description

Background summary

Appendicitis is the most common reason for abdominal surgery in children. Appendicitis and surgery performed on acute appendicitis still causes morbidity and complications. The first step in prevention would therefore be to know more about the pathogenesis of appendicitis.

Appendicitis is caused by obstruction of the lumen; this may be due to a feacolith or enlarged peri- appendiceal lymph nodes. It has been hypothesized that specific viral or bacterial infections causes enlargement of these lymph nodes and may therefore play a role in the pathogenesis of acute appendicitis in children.

Study objective

The objective is to investigate the correlation between bacterial/viral gut

infections and acute appendicitis in children.

Study design

Prospective observational multicenter study

Study burden and risks

There is no direct benefit for the patients who are participating in this study. But the burden for the patients is also minimal. The extra blood sample of 6 ml will be collected simultaneously with the routine blood sampling. Therefore, no extra venapuncture is necessary. The biopsy from the base of the appendix will be taken after excision and therefore gives no additional risk. Furthermore, the collection of a fecal sample is not invasive and can be send to the UMCG, so it does not extent the time at the emergency department. Finally, filling in the questionnaire is not a burden for the health of the children.

This research may be in the future an important contribution to diagnose children with suspected appendicitis faster, and contributes to possible new treatment methods for appendicitis.

Contacts

Public

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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

Children between 5 and 18 years old, who are referred by first line health care with the suspicion of acute appendicitis. Healthy children between 5 and 18 years old

Exclusion criteria

Severe co-morbidity like malignancy, resent abdominal surgery and known inflammatory bowl disease. Pregnancy

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	248
Туре:	Anticipated

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Ethics review

Not approved	
Date:	26-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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 CCMO **ID** NL57448.042.16