MR Imaging of acute appendicitis in children

Published: 17-02-2009
Last updated: 06-05-2024

To determine the value of MRI in a consecutive series of pediatric patients suspected for acute appendicitis

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

Summary

ID

NL-OMON33715

Source
ToetsingOnline

Brief title
MRI appendicitis children

Condition

- Gastrointestinal infections
- Ancillary infectious topics

Synonym
appendicitis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Siemens Nederland,subsidie foreest medical school mca aangevraagd

Intervention

Keyword: abdominal, appendicitis, children, mri

Outcome measures

Primary outcome

Primary outcome measures are the sensitivity, specificity, positive and negative predictive value and inter observer agreement of MRI in diagnosing acute appendicitis as compared to the reference standard. The MRI findings will be compared to the findings at imaging of the standard diagnostic work-up that preceded MRI (US). The diagnostic value of specific MRI characteristics for appendicitis will be calculated.

Secondary outcome

Secondary outcome measures are the acceptance of MRI as compared to US by a questionary and the cost effectiveness of MRI.

Study description

Background summary

Acute appendicitis is the most common cause of acute abdominal pain requiring surgery in children, and typically occurs in older children and young adults.
The main cause of appendicitis is obstruction of the appendiceal lumen that leads to diminished lymphatic and venous drainage, which in turn can result in bacterial infection of the appendiceal wall.
Appendicitis presents with periumbilical pain typically descending to the right lower quadrant, as well as nausea and vomiting in 50% of the patients. If presentation is less specific, it can be difficult to differentiate acute appendicitis from other sometimes non-surgical conditions that result in acute abdominal pain. In these cases, additional imaging is necessary to avoid delay of diagnosis or unnecessary surgical intervention. The main complication of a delayed diagnosis is perforation, which can lead to abscess formation, peritonitis, and even death. The prevalence of appendiceal perforation in various pediatric series ranges from 23% to 73%. Graded-compression US is the

imaging method of choice, and high sensitivity and specificity can be achieved when employed by experienced examiners. However, the appendix is not always visible, especially if the appendix has a retrocoecal location or if the appendix is perforated. When further evaluation is necessary, other imaging modalities play an important role in diagnosis. CT examination in appendicitis has been validated and the number of CT scans performed in the presurgical diagnosis of appendicitis is increasing rapidly. However the lifetime risk of radiation-induced fatal cancer is estimated to be considerably higher for fetal, pediatric and adolescent exposure than for adult exposure. There are several publications describing good results with MR imaging of appendicitis in adults, mainly involving pregnant patients. However pediatric patients have a different constitution (in general less abdominal fat and the imaging characteristics of the appendix may be different (because of lymphoid tissue). As far as we know no prospective studies have been done in children, even though this population may benefit the most from this technique. One of the reasons for this may be that up to recently the examination time was long, resulting in motion artifacts. The introduction of ultra-fast sequences shortens the examination time, resulting in less motion artifacts, which is especially useful in children.

Study objective

To determine the value of MRI in a consecutive series of pediatric patients suspected for acute appendicitis

Study design

This will be a prospective study performed at the department of Radiology of the Medical Center Alkmaar. 100 consecutive pediatric patients suspected of appendicitis will undergo ultrasound and MR Imaging.

Study burden and risks

There is no burden or risk with participation of the study.

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

acute right lower quadrant pain
elevated CRP
abdominal tenderness

Exclusion criteria

recent abdominal operation
contra-indications for MR Imaging

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2009
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL24760.094.08