MR imaging of acute appendicitis in adults

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Primary Objective: To determine the sensitivity and specificity of MRI in a consecutive series of adult patients suspected for acute appendicitisSecondary Objective(s): Is MRI of additional value in adult patients with inconclusive US? And is...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON33952

Source
ToetsingOnline

Brief title
MRI appendicitis adults

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, adults, appendicitis, 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. The value of DWI will be analyzed.

Secondary outcome

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

Study description

Background summary

Acute appendicitis is the most common cause of acute abdominal pain requiring surgery in adults, typically the adolescent. 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 adult 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 cross-sectional imaging modalities play an important role in diagnosis. Clinical guidelines advice a CT-scan in case the US is inconclusive. 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 adolescent exposure. There are some publications describing good results with MR imaging of appendicitis in adults, mainly involving pregnant patients. The introduction of ultra-fast sequences shortens the examination time, resulting in a better visualisation of the abdomen, without exposing the patient to radiation.

Study objective

Primary Objective: To determine the sensitivity and specificity of MRI in a consecutive series of adult patients suspected for acute appendicitis
Secondary Objective(s): Is MRI of additional value in adult patients with inconclusive US? And is Diffusion Weighted Imaging (DWI) of additional value in the imaging of adult patients with suspected appendicitis.

Study design

This will be a prospective study performed at the department of Radiology of the Medical Center Alkmaar. 100 consecutive adult 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
Adults (18-64 years)
Elderly (65 years and older)

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:	Will not start
Start date (anticipated):	01-01-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-04-2009
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	NL25413.094.08