

# Research in Acute appendicitis and magnetic resonance imaging.

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To determine the sensitivity and specificity and positive and negative predictive value of MRI in a consecutive series of pediatric patients suspected for acute appendicitis.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27091

### Bron

NTR

### Verkorte titel

RADIANCE-trial

### Aandoening

Acute appendicitis

## Ondersteuning

**Primaire sponsor:** MCA Alkmaar

**Overige ondersteuning:** Foreest instituut

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

To determine the sensitivity and specificity and positive and negative predictive value of MRI in a consecutive series of pediatric patients suspected for acute appendicitis.

### Onderzoeksopzet

1. The histopathologic findings if the patient is operated upon;

2. Diagnosis after a follow-up period of 3 months in all patients.

In patients who were treated conservatively (e.g. no appendicitis, or a different cause for the pain was detected) appendicitis will be ruled out, if in those 3 months no further operation upon the appendix was performed.

US and MRI findings will be compared to these study end points.

### **Onderzoeksproduct en/of interventie**

1. Ultra Sound (US);
2. Magnetic Resonance Imaging (MRI).

## **Contactpersonen**

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## **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pediatric patients (4-18 years of age) with suspected appendicitis defined as right lower abdominal quadrant pain with or without elevation of CRP;
2. Patients, or a legal representative, must be able to give informed consent, and the consent must be obtained prior to the MR Imaging.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Abdominal surgery in the 6 weeks prior to inclusion;
2. Contra-indication for undergoing MRI, for example presence of a pacemaker or cardioversion device;
3. A psychiatric, addictive, or any disorder that compromises ability to give truly informed consent for participation in this study.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
<b>Controle:</b>	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

## Ethische beoordeling

Positief advies

Datum: 06-02-2009

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL1584
NTR-old	NTR1664
Ander register	METC Alkmaar : M08-059
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A