# The diagnostic accuracy of magnetic resonance imaging for acute appendiciitis

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We propose to assess the accuracy of MRI in a multicenter diagnostic accuracy study that will include a consecutive series of patients from the general population with suspected acute appendicitis. Patient acceptance and cost-effectiveness will also...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

## Summary

#### ID

NL-OMON32752

**Source** ToetsingOnline

**Brief title** Magnetic resonance imaging for acute appendicitis

## Condition

• Gastrointestinal inflammatory conditions

**Synonym** Acute appendicitis is the widely known name

#### **Research involving** Human

## **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: ZonMw;NWO

1 - The diagnostic accuracy of magnetic resonance imaging for acute appendiciitis 4-05-2025

#### Intervention

Keyword: acute appendicitis, Diagnostic accuracy, Magnetic resonance imaging

#### **Outcome measures**

#### **Primary outcome**

Sensitivity, specificity, predictive values of MRI for acute appendicitis

#### Secondary outcome

Inter-observer variability, patient acceptance, and cost-effectiveness.

# **Study description**

#### **Background summary**

In the Netherlands 30,000 individuals are suspected with acute appendicitis annually. The clinical diagnosis acute appendicitis is plagued by high negative appendectomy rates (10% to 41%) and missed diagnoses (12%). Ultrasound (US) and computed tomography (CT) are widely used to substantiate the clinical diagnosis. US has considerable limitations in accuracy, as it generates too many false negative results. Although CT is more accurate, this technique is still inaccurate in 12% of patients and results in considerable ionizing radiation exposure in often young individuals.

MRI could be an alternative form of imaging. MRI (1) is more accurate than US and possibly CT, (2) uses no ionizing radiation, (3) and requires no contrast agent. So far, MRI has been studied in series limited in size, primarily including selected (pregnant) patients with substantial differences in prevalence (10% versus the usual 60%) and with a spectrum of disease substantially different from general clinical practice. These results do not justify introducing MRI as first line imaging technique.

#### **Study objective**

We propose to assess the accuracy of MRI in a multicenter diagnostic accuracy study that will include a consecutive series of patients from the general population with suspected acute appendicitis. Patient acceptance and cost-effectiveness will also be evaluated.

#### Study design

A multicenter diagnostic accuracy study in which the included patients undergo

2 - The diagnostic accuracy of magnetic resonance imaging for acute appendiciitis 4-05-2025

imaging according to the draft Dutch acute appendicitis guideline: initial US in all and subsequent CT in non diagnostic US cases (i.e. US not confirming acute appendicitis). MRI is performed in all patients, but not used for patient management. Reference standard is the final diagnosis assigned by an expert panel, based on all available information including 3-months follow-up, except MRI findings. Study period is two years (17 months inclusion period).

#### Intervention

MRI

#### Study burden and risks

MRI is a non-invasive examination without ionizing radiation. Hereby participating in this study is associated with minor burden and risks. The burden for the patients is mainly caused by waiting for and undergoing the MRI scan. However, all MRI scan will be performed within two hours. The MRI scan itself will be made in approximately 30 minuten, of which the patient will spend approximately 15 minutes within the MRI machine.

## Contacts

Public Academisch Medisch Centrum

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## **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

#### **Inclusion criteria**

Clinically suspected appendicitis

## **Exclusion criteria**

Age <18 years Pregnancy Critically ill patients that need intensive vital organ function monitoring for life-support (for example patients in shock) Patients with a contra-indication for MRI (pacemaker, claustrofobia)

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Other	

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	230
Туре:	Anticipated

4 - The diagnostic accuracy of magnetic resonance imaging for acute appendiciitis 4-05-2025

# **Ethics review**

Approved WMO Application type: Review commission:

First submission 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** CCMO ID NL29694.018.09