OPTimizing IMaging in APpendicitis.

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In patient with clinically suspected appendicitis, imaging is needed to substantiate the clinical diagnosis. Imaging accuracy of US and CT is suboptimal, and the associated use of ionizing radiation and iodinated contrast medium are major drawbacks...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20262

Bron
NTR

Verkorte titel
OPTIMAP

Aandoening

appendicitis; magnetic resonance imaging; MRI.

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum Amsterdam
Overige ondersteuning: Zon MW Health Care Efficiency Research programme. Projectnumber 171001005

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic accuracy of MRI in detecting acute appendicitis will be calculated with corresponding 95% confidence intervals, by comparing the results of MRI with the final diagnosis assigned by the expert panel. We will determine the sensitivity, specificity,

predictive values, inter-observer agreement and patient acceptance of MRI in a consecutive series of patients suspected for acute appendicitis.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

We propose to assess the sensitivity, specificity, predictive values and inter-observer agreement 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.

The study builds on the experience, collaboration, logistics and infrastructure developed for the successful OPTIMA study in patients with acute abdominal pain. Included patients undergo 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. Given the anticipated MRI sensitivity (90%) and specificity (95%) and the proportion of patients with acute appendicitis (60%), a study group of 230 patients is required for sufficient precision. Study period is two years (17 months inclusion period).

Doel van het onderzoek

In patient with clinically suspected appendicitis, imaging is needed to substantiate the clinical diagnosis. Imaging accuracy of US and CT is suboptimal, and the associated use of ionizing radiation and iodinated contrast medium are major drawbacks.

MRI is a potential replacement. Introducing MRI may reduce the negative appendectomy rate, the number of cases of missed appendicitis and obviate radiation exposure. Accuracy of MRI seems at least comparable to CT, but MRI has only been evaluated in limited series primarily evaluating selected patients. Given the high intrinsic contrast resolution of MRI, it may be even more accurate than CT for certain alternative conditions in patients with suspected appendicitis, such as gynaecological conditions. Our study will evaluate the accuracy, reproducibility and patient acceptance of MRI as compared to US and CT.

Onderzoeksopzet

All patients will have 3-month follow up. General practice physicians will be contacted to assure patients did not have an appendectomy in another hospital, or an alternative diagnosis was assigned. An expert panel consisting of two surgeons and a radiologist, will assign a final diagnosis after a follow-up period of 3 months, based on all available information: clinical information, imaging findings (except MRI findings), surgery, pathology and follow up.

Onderzoeksproduct en/of interventie

Consenting patients will undergo standard practice, as defined in the draft Dutch guideline on the diagnostic work-up of patients with suspected appendicitis: initial US followed by CT in case of a non diagnostic US (i.e. US not confirming the diagnosis appendicitis). Additionally, all patients undergo MRI, with the MRI reader blinded from the results of the other imaging methods. As the reference standard we will use a final diagnosis assigned based on all available data after 3 months follow-up.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible are adult patients, 18 years or older, with clinically suspected acute appendicitis presenting at the ED. No patients should be excluded based on the clinical condition: ‘clinically obvious’ cases should also be included (restriction see exclusion criteria).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Excluded are patients with conditions known to be incompatible with MRI use, such as a pacemaker, known claustrophobia, and critically ill patients that need intensive vital organ function monitoring for life-support.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2010
Aantal proefpersonen:	230
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-12-2009
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	NL2031
NTR-old	NTR2148
Ander register	METC AMC / ZonMw : MEC 09/266 / 171001005
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A