"Evaluating small bowel wall in Crohn's disease: a comparison of MR enterography and contrast-enhanced ultrasound"

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

Summary

ID

NL-OMON33145

Source
ToetsingOnline

Brief title
"Contrast-enhanced ultrasound in the diagnosis of Crohn's disease"

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: stichting Maag-;darm-;leverziekten Arnhem (gelieerd aan Maatschap MDL-artsen Rijnstate); financieering arts onderzoeker

Intervention

Keyword: contrast-enhanced ultrasound, Crohn's disease

Outcome measures

Primary outcome

The disease activity scores at CE-US (qualitative and quantitative), MRE and

ileocolonoscopy and clinical activity score.

Secondary outcome

Not applicable

Study description

Background summary

Magnetic resonance enterography/enteroclysis (MRE) and ileocolonoscopy are the standard procedures in the primary diagnosis and follow-up of inflammatory disease of the small bowel.
Bowel ultrasound is a non-invasive and inexpensive modality which has also been proposed for diagnosing small bowel Crohn*s disease, but because of limited accuracy has not yet been incorporated in the daily practice. Contrast enhanced ultrasonography with intravenous contrast has been shown to improve the acuracy of ultrasound in detecting disease activity in patients already known with small bowel CD.
No studies have yet examined the acuracy and feasibility of CE-US in patients suspected of having small bowel CD in comparison with MR enterography, and the correlation of these findings with the level of inflamation assessed by ileocolonoscopy and histology. Our hypothesis is that contrast enhanced ultrasonography is just as accurate as MR enterography in the diagnosis of small bowel Crohn*s disease.

Study objective

The aim of the study is to assess the accuracy and feasibility of contrast enhanced ultrasonography (CE-US), in the primary diagnosis and relapse during follow up of small bowel CD, compared to MR enterography. Furthermore we

attempt to determine the correlation between disease severity assessed by ileocoloscopy and histology compared to the ultrasonographic findings.

Study design

A prospective, cohort study.
Within one week after the confirmation of the diagnosis Crohn's disease (ileocolonoscopy with biopsies) all patients will receive the CE-US followed by the magnetic resonance enterography (MRE).

Study burden and risks

The burden for the individual patient, associated with participation to the study could be related to the period of time spent on the radiology department for undergoing the CE-US (approximately 45 minutes longer), which will be performed on the same day with the MRE. Eventual discomfort during the CE-US could be related to possible adverse reaction of the contrast agent, such as headache and nausea (2,3%), injection site reactions (1,7%). Furthermore is there a very small risk for een allergic reaction

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

- age between 18-65 years old;
- confirmed Crohn*s disease by ileocolonoscopy with biopsies;
- informed consent;

Exclusion criteria

- cardiac failure (acute or chronic NYHA class II -IV) or other heart disease (unstable angina pectoris, recent acute coronary syndrome, severe rhythm disorders), right-to-left cardiac shunts, uncontrolled systemic hypertension, severe pulmonary hypetension and adult respiratory distress syndrome, which contraindicate the use of intravenous contrast during CE-US;
- chronic end stage kidney disease (risk for nephrogenic systemic sclerosis by use of MRI contrast agent: Gadolinium);
- patients having absolute contraindications for the MRI (intracorporal metal clips, neurostimulator, insuline pomp or pacemaker);
- patients with an acute abdomen and indication for surgery;
- pregnancy and lactation;

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	15-09-2009
Enrollment:	150
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-07-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2009-013503-55-NL
CCMO	NL28132.091.09