MRI of the small bowel and colon in determining disease activity in patients with Crohn*s disease

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To study MRI of the small bowel and colon in determining disease activity in patients with Crohn*s disease.

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

Summary

ID

NL-OMON36153

Source
ToetsingOnline

Brief title
VIGOR++

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Crohn's disease, IBD, MRI, VIGOR++

Outcome measures

Primary outcome

The main study parameter will be the sensitivity and specificity of MRI of the colon and small bowel in grading disease activity in CD patients. Also, the added value of MRI of the colon willl be compared to routine MRI of the small bowel. Colonoscopy will serve as the reference standard.

Secondary outcome

The secondary endpoints will be the comparison of the MRI findings (additional MR imaging with DWI, T1-map and dynamic imaging (DCE-MRI)), compared to the Harvey Bradshaw index and C-reactive protein (CRP) for grading disease activity in CD patients.

The study will acquire these data in order to develop and assess ICT tools for objective measurement of features of Crohn*s disease such as the bowel wall thickness. For the developing of the ICT tools we will share our data with European collaborators in the framework of an EU FP7 consortium (VIGOR++).

Study description

Background summary

Crohn*s disease (CD) is a transmural granulomatous inflammatory bowel disease characterized by aphthous ulceration, cobblestoning, strictures and fistula formation, which can affect any part of the gastrointestinal tract. However, locations of predilection are the terminal ileum and colon. The disease

typically runs a chronic relapsing and remitting course and is associated with prominent extra-intestinal manifestations and an increased incidence of gastrointestinal cancer.
Grading of disease severity is important to be able to optimally determine treatment strategy and response to treatment. In clinical practice, assessment of activity can be performed by the Crohn*s Disease Activity Index (CDAI) or the Harvey Bradshaw index, laboratory inflammation markers as C-reactive protein, and/or endoscopy (scored in Crohn*s Disease Endoscopic Index of Severity (CDEIS) and in case of ileal resection also scored in Rutgeerts* score).
Ideally, an activity score should be objective, reproducible, quantifiable and non-invasive. However, to none of the abovementioned methods all four criteria are applicable; the CDAI or Harvey Bradshaw index is a clinical index that incorporates subjective elements and therefore partly reflects patients* perception of disease severity and laboratory findings can be unchanged in the presence of altered disease activity. Endoscopy is an invasive procedure with a burdensome bowel preparation. Moreover, none of the abovementioned methods allows precise transmural and extra intestinal evaluation of disease.
Abdominal MR-imaging using luminal and intravenous contrast medium combines transmural and extra-intestinal evaluation and can accurately show presence of disease (e.g. stenosis, bowel wall thickening, abscess, fistula). Moreover, MRI can discriminate between active and fibrotic disease as MRI studies undertaken to determine Crohn*s disease activity in the small and large bowel have indicated that a pathological increase in bowel wall enhancement after intravenous contrast administration of Gadolinium is a useful discriminatory sign of active disease.
Many studies have confirmed the role of MRI in the evaluation of CD, in the detection of small bowel lesions and complications and the assessment of disease activity. Available evidence indicates that MRI can be useful too for the detection of activity and assessment of severity in colonic CD, but have been investigated less extensively. Detection of extracolonic complications and information regarding the whole abdominal cavity are the main strengths of this technique and might obviate colonoscopy

The evaluation of MRI in Crohn*s disease is initially performed by radiologists, which leaves room to variation in interpretation. An objective method to grade disease activity would be important for patient management as well for pharmaceutical studies. Therefore, the data acquired during this study of consenting patients will also be used for the development and validation of ICT tools to do so.

Study objective

To study MRI of the small bowel and colon in determining disease activity in patients with Crohn*s disease.

Study design

A prospective observational study that evaluates the accuracy of additional MRI of the colon in patients with Crohn*s disease undergoing MRI of the small bowel.

Study burden and risks

Patients will undergo an ileocolonoscopy, venapuncture and MRI scan as part of their clinical follow-up. For this study, three additional sequences will be made during the MRI scan, which causes 15 minutes of extra scan time. Also, patients have to fill in a questionnaire, the Harvey Bradshaw index which will take two minutes to complete.
No side-effects or risks have been reported on MR imaging, some patients may experience claustrophobia.

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

Proven Crohn*s disease (by endoscopy or histopathology)
Scheduled to undergo an ileocolonoscopy as part of their clinical follow-up
Scheduled for MRI as part of their clinical follow-up

Exclusion criteria

Under 18 years of age
General contraindications to MRI (claustrophobia, pregnancy, sever renal insufficiency) and MRI intravenous contrast agent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	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	ID
CCMO	NL36453.018.11