Evaluation of the predictive value of Dynamic MRI in determining treatment response in perianal fistulizing Crohn*s disease before and after treatment with Infliximab

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To study whether dynamic MRI can predict treatment response and long term outcome in patients with Crohn*s disease.

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

Summary

ID

NL-OMON32206

Source
ToetsingOnline

Brief title
DCE-MRI in predicting treatment response perianal fistulizing CD.

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Crohn's disease, dynamic MRI, Fistula

Outcome measures

Primary outcome

Predictive value of DCE-MRI before anti-TNF treatment and during treatment (6 weeks) in predicting or identifying early response as compared to the PDAI after 6 weeks and 12 weeks.

Predictive value of DCE-MRI after twelve weeks of anti-TNF treatment as compared to the PDAI after 1 year.

Secondary outcome

DCE-MRI compared to the MRI-based score, CRP.

Study description

Background summary

Crohn*s disease (CD) is a chronic, segmental, transmural inflammatory bowel disease (IBD). Perianal fistulas are reported to occur in up one third of patients. MR imaging is an effective imaging modality in the evaluation of patients with perianal CD as it can accurately demonstrate localization and extent of disease including clinically undetected fistula or abscess. Many patients with perianal Crohn*s disease are treated with Infliximab, a monoclonal antibody against tumor necrosis factor. Infliximab has been shown to reduce the number of Crohn related fistulas. Clinical evaluation is inaccurate in determing treatment response. Initial studies have shown the potential of MRI in establishing the presence or absence of treatment response.
In order to provide a more accurate disease index Van Assche et al developed an MRI-based score of disease severity based on static MRI for patients with perianal fistulizing CD. This score has limitations (reproducibility, no

external validation). A recent pilotstudy from the AMC has shown that dynamic contrast-enhanced MRI (DCE-MRI) before treatment can possibly add valuable information about disease activity in perianal CD. We want to determine with this study the potential value of MRI, now that we can assess the whole course of the fistula with the use of 3T MRI (In the previous study we could only evaluate some selectected slices) and the possibility of this technique to predict during and immediately after treatment the response/remission.

Study objective

To study whether dynamic MRI can predict treatment response and long term outcome in patients with Crohn*s disease.

Study design

Prospective observational study. We will study a cohort of consecutive patients with perianal Crohn*s disease with DCE-MRI before and after remission induction therapy with Infliximab after 6 weeks, 12 weeks, and 1 year.

Study burden and risks

MRI is a routine examination in patients with Crohn*s disease and is routinely performed with intravenous contrast medium.
Patients will undergo 4 MRI scans as part of their clinical follow-up. For this study a 5 minute additional MRI sequence will be performed during each of the MRI scans. The scan will last 45 minutes. Also they have to fill in the PDAI after each MRI scan. This will cost 5 minutes (total of 20 minutes). patients have to undergo a venapuncture three times, one time for study purposes only. No side-effects or risks have been reported for MR imaging provided that contra indications are considered. 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 and/or histopathology
draining perianal fistula

Exclusion criteria

under 18 years of age
general contraindications to MRI (claustrophobia, pregnancy, renal insufficiency, pacemakers).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	33
Type:	Anticipated

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	NL22852.018.08