

Evaluatie van dynamische MRI als voorspeller van respons op behandeling in patienten met perianale fistels bij de ziekte van Crohn.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28234

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Crohn, perianal fistula, perianale fistel.

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

Predictive value of DCE-MRI before treatment and during treatment (12 weeks) in predicting

or identifying early response as compared to the PDAI (12 weeks).

Secondary outcome

Predictive value of DCE-MRI compared to the MRI-based score, CRP.

Study description

Background summary

Background:

Crohn's disease (CD) is an inflammatory bowel disease (IBD). Perianal fistulas are reported to occur in up to 38% 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 medicinal therapy. Clinical evaluation is inaccurate in determining treatment response. Initial studies have shown the potential of MRI in establishing the presence or absence of treatment response.

A recent study from our center (MEC number 04/271) has shown that dynamic contrast-enhanced MRI (DCE-MRI) before treatment can possibly add valuable, objective information about disease activity in perianal CD.

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 two times after remission induction therapy.

Study population:

Adult patients visiting the AMC IBD outpatients' clinic with proven CD and a draining perianal fistula.

Main study parameters/endpoints:

The main study endpoint will be the predictive value of DCE-MRI compared to PDAI.

Patients participating will undergo a MRI scan 3 times; which is a routine procedure in these patients. For this study a 5 minute additional MRI sequence will be performed during each MRI scan. Also patients have to give one additional venous blood sample and fill in the PDAI,

a questionnaire, three times.

Study objective

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

Study design

1. Before therapy (week 0): DCE-MRI, PDAI (question list) and CRP (laboratory value);
2. Week 12 after starting therapy: DCE-MRI, PDAI and CRP. One year after therapy: DCE-MRI and PDAI.

Intervention

MRI before start therapy, after 12 weeks, after one year.

Contacts

Public

Meibergdreef 9
M.L.W. Ziech
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5663740

Scientific

Meibergdreef 9
M.L.W. Ziech
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5663740

Eligibility criteria

Inclusion criteria

1. Crohn's disease;

2. Draining perianal fistula;
3. Starting with therapy for perianal fistula.

Exclusion criteria

1. Age < 18 years;
2. Contraindications for MRI (pregnancy, renal insufficiency, allergy to contrast media, metallic implants).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2008
Enrollment:	33
Type:	Actual

Ethics review

Positive opinion	
Date:	01-09-2009
Application type:	First submission

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
NTR-new	NL1872
NTR-old	NTR1986
Other	METC Academic medical center : 08/116
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A