

# EVALUATION OF DYNAMIC MRI WITH T1-MAPS CORRELATED WITH HISTOPATHOLOGY IN PATIENTS WITH CROHN'S DISEASE.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON19958

### Source

NTR

### Brief title

DCE-MRI correlation with PA in CD

### Health condition

Crohn's disease, ziekte van Crohn

## Sponsors and support

**Primary sponsor:** Academic Medical Center, department of radiology

**Source(s) of monetary or material Support:** Academic Medical Center, department of radiology

## Intervention

## Outcome measures

### Primary outcome

1 - EVALUATION OF DYNAMIC MRI WITH T1-MAPS CORRELATED WITH HISTOPATHOLOGY IN PATIENT ...  
5-05-2025

The main study parameter will be the accuracy of detecting disease activity and efficacy of DCE MRI at MR in patients with proven Crohn's disease as compared to histopathology.

## **Secondary outcome**

The secondary study parameters will be the accuracy of detecting disease activity on DCE-MRI as compared to CDAI and CRP. Also the aspect of the bowel wall (serositis or normal) as seen during surgery will be compared to the MRI and the histology.

# **Study description**

## **Background summary**

Rationale:

Crohn's disease (CD) is a transmural inflammatory bowel disease. Grading of severity of disease is important to be able to optimally determine treatment strategy and response to treatment. Abdominal MR-imaging using luminal and intravenous contrast medium combines transmural and extra-intestinal evaluation and can accurately show presence of disease. Moreover, MRI can discriminate between active and fibrotic disease as MRI studies undertaken to determine CD 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.

Earlier studies have shown that dynamic contrast enhancement curves shown a correlation with active disease in patients with Crohn's disease related perianal fistulas. We expect this also to be the case in luminal Crohn's disease.

Objective:

To determine the correlation between enhancement curves at DCE-MRI and the level of histopathological activity in patients with active luminal CD.

Study design:

Prospective observational study. Patients will undergo a venapuncture and MRI scan as part of clinical routine before surgery. For this study, a dynamic sequence (DCE-MRI) sequence will be made during the MRI scan; therefore the scanning time will be prolonged for 15 minutes. Total scanning time will be 50 minutes. Also, patients have to fill in 1 questionnaire, the CDAI (duration less than 5 minutes). After surgery the resected bowel will be scanned in the MRI for anatomical reference. The inclusion period of the study will be 2 years.

Study population:

Twenty adult patients with proven Crohn's disease who are scheduled to undergo small-bowel surgery for active M. Crohn will be included after informed consent.

### **Study objective**

To determine the correlation between enhancement curves at DCE-MRI with T1-map and the level of histopathological activity.

### **Study design**

Before surgery, the patient will undergo an abdominal MRI.

### **Intervention**

Preoperative MRI with extra dynamic sequence.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Proven Crohn's Disease (by endoscopy or histopathology);
2. Scheduled to undergo small-bowel surgery for Crohn's Disease.];

3. Scheduled to undergo a preoperative MRI.

## Exclusion criteria

1. Age < 18 years;
2. General contraindications for MRI (pacemaker, claustrophobia, renal insufficiency and pregnancy).

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
<b>Control:</b>	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	20
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	04-02-2010
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	NL2084
NTR-old	NTR2201
Other	MEC AMC : 08/348
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A