# Evaluation of dynamic MRI with T1-maps correlated with histopathology in patients with Crohn's Disease

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

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

# **Summary**

### ID

NL-OMON32582

**Source** ToetsingOnline

#### **Brief title**

Dynamic MRI correlated with histopathology in patients with Crohn's Disease

### 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: Ministerie van OC&W

### Intervention

Keyword: Crohn, DCE-MRI, Histopathology, T1-map

### **Outcome measures**

#### **Primary outcome**

The main study parameter will be the accuracy of detecting disease activity and efficacy of DCE MRI with T1 mapping and DWI at MR in patients with proven Crohn\*s disease as compared to histopathology.

#### Secondary outcome

1. To determine the correlation between Gadolinium concentration of the

pathological bowel wall and histopathological activity.

2. To determine the correlation between enhancement curves at DCE-MRI and CDAI,

CRP.

3. To determine the correlation between Gadolinium concentration of the

pathological bowel wall and CDAI, CRP.

4. To determine the correlation between histopathology and enhancement patterns

of the colonic wall.

5. To determine the correlation between histopathology and DWI.

# **Study description**

#### **Background summary**

Crohn\*s disease (CD) is a transmural granulomatous inflammatory bowel disease, characterized by remissions and exacerbations. Grading of severity of disease is important to be able to optimally determine treatment strategy and response to treatment. At present there is no satisfying gold standard for active Crohn\*s disease. 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.

Hypothetically, calculation of the absolute T1-values in tissue before and after intravenous injection of Gadolinium would provide objective measurements of the Gadolinium-uptake. This so-called T1-mapping in abdominal MRI could indeed be used to determine activity of disease in an objective, quantifiable, reproducible manner and could be a valuable tool to the present imperfect disease scores such as CDAI (Crohn\*s Disease Activity Index) and CRP. Thereby, conventional MRI has limitations in establishing remission or limited disease activity, and dynamic MRI with T1-mapping and diffusion weighted imaging (DWI) might be valuable to identify these entities. Our hypothesis is that restriction of diffusion can be seen in inflamed tissue that could be an aid in diagnosing disease activity.

### **Study objective**

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

### 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) with T1-map and DWI 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). ). For anatomical reference, the resected bowel will also be scanned in the MRI. The inclusion period of the study will be 2 years.

### Study burden and risks

Patients will undergo MRI scan as part of their clinical pre-operative assessment. For this study, an additional dynamic sequence with T1-mapping sequence and DWI sequence will be made during the MRI scan and patients have to fill in 1 questionnaire, the CDAI. The MRI scan will last 50 minutes, including 15 minutes additional scanning for research purposes. No side-effects or risks have been reported on MR imaging provided that contra-indications are taken into account. Some patients may experience claustrophobia.

# Contacts

**Public** Academisch Medisch Centrum

PB 22660 1100 DD NL **Scientific** Academisch Medisch Centrum

PB 22660 1100 DD NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age Adults (18-64 years) Elderly (65 years and older)

# **Inclusion criteria**

Crohn's Disease Scheduled for elective surgery of the small bowel > 18 years old

# **Exclusion criteria**

general contraindications for MRI (pacemaker, pregnancy, renal insuffiency, claustrophobia)

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2009
Enrollment:	20
Туре:	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** CCMO **ID** NL24732.018.08