# High frequency and dynamic contrast-enhanced ultrasound for treatment follow up of patients with Crohn*s disease.

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The primary objective of this study is to evaluate the sensitivity of high frequency sonography combined with DCE-US in the follow-up of treatment efficacy in patients experiencing acute deterioration of Crohn's disease (CD) started on anti-TNF…

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

## Summary

### ID

NL-OMON50449

**Source**
ToetsingOnline

**Brief title**
CEUS for treatment follow-up in Crohn's disease

### Condition

- Gastrointestinal inflammatory conditions

**Synonym**
chronic intestinal inflammation, Crohn's 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:** Contrast, Crohn's disease, ultrasound

## Outcome measures

### Primary outcome

Ultrasound parameters: length affected intestine, wall thickness (mucosa, submucosa, muscularis propria, stratification), thick muscularis mucosae, fistula, stenosis, motility, creeping fat, vessel index CD, CEUS index, mean transit time, blood volume, blood flow.

### Secondary outcome

Endoscopic disease activity, biochemical disease activity (inflammatory parameters), clinical disease activity (HBI).

# Study description

### Background summary

The evaluation of early treatment response in IBD is often limited to clinical and biochemical evaluation while endoscopy or other imaging is typically performed later. Early evaluation of treatment response is of great importance since it gives clinicians the opportunity to optimize the treatment strategy. Repeated X-ray examinations pose potential health risks due to radiation while MRI is resource intensive and less available than ultrasound. Ultrasound therefore seems to be the most suitable imaging tool during follow up. Several longitudinal studies have investigated treatment outcome with ultrasonography. Both increased bowel wall thickness and contrast-enhancement have been related to the need for surgery, relapse after surgery and monitoring treatment effect. In a recent study Quaia et al. showed a difference in relative perfusion three months after treatment initiation between treatment responders and non-responders. However, this was a cross-sectional study and therefore did not include data from treatment start or data on bowel wall thickness. Nylund et al. recently published a pilot study which showed that patients with treatment failure after one month had increased perfusion and a

thickened proper muscle layer. These results suggest that early findings in treatment follow-up may give prognostic information that may guide treatment decisions, but the study was underpowered to look at other outcomes.

### Study objective

The primary objective of this study is to evaluate the sensitivity of high frequency sonography combined with DCE-US in the follow-up of treatment efficacy in patients experiencing acute deterioration of Crohn's disease (CD) started on anti-TNF treatment compared to ileocolonoscopy as the reference standard.

### Study design

Single center, prospective observational study with 6 months follow-up

### Study burden and risks

Blood will be drawn four times in six months to measure various inflammatory markers as part of standard care. Patients will be subjected to four trans-abdominal ultrasound examinations with contrast enhancement and two ileocolonoscopies (standard care). Only patients that need treatment in the frame of their usual care will be included. Trans-abdominal ultrasound is a safe procedure that uses high frequency sound waves for the visualization of internal organs. Contrast enhanced ultrasound has a very low risk. Anaphylactic reactions to Sonovue contrast solution have been reported in less than 1 in 10.000 patients.
Implementation contrast enhanced ultrasound for treatment follow-up in CD patients may result in a reduced need for ileocolonoscopy and MRI, thereby reducing costs and the burden for patients. Waiting times for ileocolonoscopy and MRI are also long whereas ultrasound can be applied on a more regular basis. Treatment decisions based on ultrasound appearance can be made *on the spot*, allowing for a point-of-care approach in CD patients.

## 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

- acute deterioration of histologically confirmed Crohn*s disease with Harvey Bradshow Index (clinical score) >= 8
- start of systemic medical treatment with TNF-α inhibitors (adalimumab or infliximab)

## Exclusion criteria

- no thickened bowel segments found on ultrasound
- use of TNF-α inhibitor last 3 months
- pregnancy
- age<18years
- chronic obstructive lung disease
- acute coronary heart disease
- clinically unstable heart disease and/or
- earlier allergic reaction to Sonovue or to its components
- ongoing gastroenteritis
- presence of an intra-abdominal abscess or a fistula
- obesity (BMI>30 kg/m2)

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-04-2016 |
| Enrollment: | 40 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 04-03-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 27-06-2016 |
| Application type: | Amendment |
| 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 | NL55713.018.15 |