# CAN CLINICAL ACTIVITY INDICES PREDICT ENDOSCOPIC AND HISTOLOGIC INFLAMMATORY ACTIVITY IN CROHN*S DISEASE?
# A validation study

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The aim of the present study is to validate this model in a Dutch CD patient population.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal signs and symptoms |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON33640

**Source**
ToetsingOnline

**Brief title**
Validation of a non-endoscopic disease activiy index in CD

### Condition

- Gastrointestinal signs and symptoms

**Synonym**
Crohn's disease, Inflammatory Bowel Disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** colonoscopy, Crohn's disease, disease activity index, endoscopic disease activity

## Outcome measures

### Primary outcome

correlation coefficient between CDEIS and new non-endoscopic index

### Secondary outcome

nvt

# Study description

### Background summary

Crohn*s disease (CD) is a chronic inflammatory disease of the GI tract. Clinical activity of the disease can be obtained by several questionnaires. The most used activity score worldwide is the Crohn*s disease activity index (CDAI). The disease activity score, reliably predicting endoscopical and histological inflammatory activity, would make such cumbersome and unpleasant procedures as endoscopies redundant. Recently, we developed this new disease activity index which is expected to reliably predict endoscopic inflammation in CD patients. We found that the following formula: number of liquid stools during one day*0.25 + C-reactive protein (mg/L) *0.1 + platelet counts (109/L) *0.01 + fecal calprotectin (mg/L) *0.001 - mean platelet volume (fL) *0.2 optimally predicts the severity of mucosal inflammation in CD patients. A good correlation between the new activity index and the CDEIS was shown (r = 0.72; P < 0.001).

### Study objective

The aim of the present study is to validate this model in a Dutch CD patient population.

### Study design

Participating patients are asked to fill out the CDAI diary, the Inflammatory Bowel Disease Questionnaire (IBDQ) and a demografic questionnaire before they undergo ileocolonoscopy. In addition to the usual demographic data, details of

duration of disease, localization and behavior of the disease (Montreal classification), current and previous medication use and previous surgeries will be obtained from the medical records of the patients.
On the day of ileocolonoscopy blood samples, feces and urine are collected. Ileocolonoscopy will be performed by the same endoscopist in all patients in each participating hospital. Endoscopic disease activity will be assessed using CDEIS (CD Endoscopic Index of severity). Representative parts of the ileum, right colon (including cecum), transverse colon, left colon (including sigmoid), and rectum will be recorded on videotape. An independent gastroenterologist will score the disease activity by reviewing all videotapes. Two biopsies will be taken from the most affected part of each segment.

**Study burden and risks**

Patients are asked to fill out three questionnaires which takes about 35 minutes, and to collect some feces.
Benefit: less often an indication for colonoscopy, which is a cumbersome procedure.

# 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

18 years of age or older
diagnosis of CD for at least 6 months
a clinical indication for ileocolonoscopy

## Exclusion criteria

A (sub)total colectomy
an ileostomy,
colostomy
active disease activity in the proximal part of the GI tract.

# 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): | 12-02-2009 |
| Enrollment: | 200 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 11-11-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 08-09-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 07-12-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL23195.041.08 |