The added value of frequent intestinal ultrasonography in the close monitoring of moderate-severe ulcerative colitis

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The primary objective of this study is to identify ultrasonographic parameters that indicate response to treatment in moderate to severe UC. Accordingly, a secondary objective is to create an ultrasonographic scoring model which predicts response.

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

Summary

ID

NL-OMON49013

Source
ToetsingOnline

Brief title
Intestinal ultrasonography in modeate/severe ulcerative colitis/DIRECT-UC

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Ulcerative colitis: inflammatory bowel (colon) 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: Colitis, Intestinal, Ulcerative, Ultrasonography

Outcome measures

Primary outcome

The main endpoint of this study will be difference in change of bowel wall

width within 26 weeks between the responding and non-responding group.

Secondary outcome

Ultrasonographic endpoints at week 0, 1, 2, 6 and between week 8 and 26:

Lumen width (millimetres)

Bowel wall thickness measured from the hyperechoic lumen to the

hypoechoic muscularis propra (millimetres)

Loss of stratification of the colon wall (yes/no)

Layer thickness (mucosa, submucosa, muscularis propria in millimetres)

Colon wall perfusion following the Limberg score

Disease extent (areas affected)

Loss of haustrae (yes/no)

Mesenteric lymph nodes (yes/no)

Abscesses (yes/no)

Examination time (minutes)

Visibility (0-3 point scale)

Faecal calprotectin

Remission < 250 mg/g

Inflammatory parameters (C-reactive protein, haemoglobin, erythrocyte count,

leukocyte count, thrombocyte count, albumin)

Remission:

CRP * 5 mg/L

Clinical disease activity scores (Mayo score, Lichtiger score, SCCAI, Oxford criteria)

Clinical response:

A decrease in Mayo score * 3

Lichtiger score <10 with a decrease of at least 3

Remission:

SCCAI * 2

Mayo score * 2 with all subscores *1

Lichtiger score * 3

Deterioration in acute severe ulcerative colitis:

Oxford criteria at day 3 to 5: *8 stools/day or >3 but <8 stools/day+CRP>45 mg/mL

Endoscopic disease activity

Response (UCEIS): decrease of 2 points in UCEIS at follow-up endoscopy at 8 to 26 weeks.

Remission (UCEIS): UCEIS * 1

Remission (Mayo): Mayo * 1

Other study parameters

Steroid refractory rate within 26 weeks

Infliximab trough levels at week 2 and 6

Colectomy rate within 26 weeks

Study description

Background summary

Ulcerative colitis (UC) is an inflammatory bowel disease characterised by a pattern of relapse and remission. A moderate to severe relapse is frequently seen during disease course and needs medical treatment. Moreover, acute severe ulcerative colitis (ASUC) is a life-threatening complication, which occurs in approximately 20% to 30% of UC patients during their disease course and results in high colectomy rates since many patients fail to medical rescue treatment.
In order to improve outcome, it is of major importance to assess effect of treatment in an early stage to adapt treatment accordingly. Several clinical and biochemical data predict failure to response but also show lack of reliability. Although endoscopy is the gold standard in evaluating UC disease activity, it is challenging to perform this exam repeatedly in patients. Indeed endoscopy is invasive, expensive and comes with adverse events and is therefore not optimal in the close monitoring of moderate to severe UC patients.
In addition to clinical, biochemical and endoscopic parameters, cross sectional imaging may show response to treatment already in the first days to weeks. Trans-abdominal ultrasound of the colon correlates well with other radiological methods (e.g MRI and CT) and colonoscopy. Furthermore, ultrasound is a method which is non-invasive, cheap and easy to perform which makes it an excellent choice to assess disease activity frequently during the first weeks of medical treatment.

Study objective

The primary objective of this study is to identify ultrasonographic parameters that indicate response to treatment in moderate to severe UC. Accordingly, a secondary objective is to create an ultrasonographic scoring model which predicts response.

Study design

Prospective longitudinal study, mono-center

Patients with at least Mayo 2 endoscopic disease activity will be eligible for inclusion. Then, at start of medical treatment, week 1, 2 and 6 an intestinal ultrasound will be performed. Furthermore, at week 2 and 6 biochemical parameters will be collected. Between week 8 and 26 patients will receive a(n) (second) endoscopy as per standard of protocol with corresponding ultrasonography and biochemical parameters.

Study burden and risks

In this group of patients it is extremely important to assess effect of treatment in an early stage. In current standard care, patients receive treatment and subsequently endoscopy is repeated within 8 to 26 weeks to show whether treatment is effective. It would be meaningful to have another complementary modality to assess disease activity that could be used more frequently and in an early stage after onset of treatment. Ultrasonography is such a promising, accurate, non-invasive and cheap modality and could therefore be a potential marker reflecting disease activity and indicating effect of treatment.
Adjacent to the standard care protocol patients will receive multiple ultrasonographic examinations. The additional burden of this study is therefore considered low whereas the potential benefit is considered high.

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

*Ulcerative colitis, histologically and endoscopically confirmed
*Endoscopically moderate to severe disease with a eMayo score *2
*Start of medical treatment
*>18 years of age

Exclusion criteria

*Age<18years
*Proctitis only
*Colonic stricture at baseline endoscopy
*Imminent need of surgery
*Sigmoidoscopy/colonoscopy older than eight weeks
*Ongoing gastroenteritis
*Cytomegalovirus (CMV) associated colitis
*Obesity (BMI >35 kg/m²)
*A normal bowel wall < 2mm at baseline ultrasonography

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2019
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2020
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	NL68692.018.19