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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22303

Source
NTR

Brief title
DIRECT-UC

Health condition

Ulcerative colitis, inflammatory bowel diseases

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The main endpoint of this study will be change in bowel wall width in millimetres within 0 to 26 weeks against the reference standard of endoscopy where response on endoscopy is defined as a decrease of at least 1 point in eMayo-score at follow-up endoscopy after 8 to 26

weeks.

Secondary outcome

• Change of other ultrasound parameters within 0 to 26 weeks against both eMayo and UCEIS at follow-up endoscopy between week 8 and 26
• Change of all ultrasound parameters within 0 to 26 weeks against clinical response according to clinical disease activity indices (Mayo, SCCAI)
• Change of all ultrasound parameters within 0 to 26 weeks against biochemical parameters (blood and faecal parameters)
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting response to treatment according to response on follow-up endoscopy between week 8 and 26 (eMayo, UCEIS)
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting remission on follow-up endoscopy between week 8 and 26 (eMayo, UCEIS)
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting response to treatment according to response based on clinical disease activity indices (Mayo, Lichtiger score)
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting remission according to clinical disease activity indices (Mayo, SCCAI, Lichtiger score)
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting response to treatment according to response based on biochemical parameters (faecal calprotectin, CRP)
• Ultrasound parameters at baseline predicting deterioration in acute severe ulcerative colitis according to Oxford criteria
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting colectomy within 0 to 26 weeks.
• Ultrasound parameters at baseline, week 1, 2 and 6 predicting failing steroid treatment

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 response on medical treatment for moderate to severe ulcerative colitis is visible on intestinal ultrasound within the first 6 weeks according to endoscopic response at 8-26 weeks

Study design

Baseline, week 1, week 2, week 6 and week 8-26

Intervention

Intestinal ultrasound

Contacts

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Eligibility criteria

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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• 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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2019
Enrollment:	54
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-07-2019
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	NL7903
Other	METC AMC : METC2019_007

Study results