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

Gepubliceerd: 26-07-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22303

Bron
NTR

Verkorte titel
DIRECT-UC

Aandoening

Ulcerative colitis, inflammatory bowel diseases

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Intestinal ultrasound

Contactpersonen

Publiek

Amsterdam UMC/AMC
Floris de Voogd

020-5661922

Wetenschappelijk

Amsterdam UMC/AMC
Floris de Voogd

020-5661922

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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/m^2)
- A normal bowel wall < 2mm at baseline ultrasonography

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-07-2019
Aantal proefpersonen:	54
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7903
Ander register	METC AMC : METC2019_007

Resultaten