Remote monitoring of IBD

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

Samenvatting

ID

NL-OMON21966

Bron
NTR

Verkorte titel
TBA

Aandoening

Inflammatory bowel disease; Crohn's disease; ulcerative colitis

Ondersteuning

Primaire sponsor: UM
Overige ondersteuning: UM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is the diagnostic test accuracy of the below listed remote monitoring tools, using ileocolonoscopy as reference:
- MIAH questionnaire with QOC test
- Mobile health Index with QOC test

- Manitoba IBD index with QOC test
- IBD-control with QOC test
- QOC test (without questionnaire)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Crohn’s disease (CD) and ulcerative colitis (UC) are chronic inflammatory bowel diseases (IBD) with a heterogeneous disease course. Recurrent mucosal inflammation or chronic subclinical inflammation results in damage to the bowel and complications like stenosis, fistula and colorectal cancer. Therefore, tight control of mucosal inflammation is important to prevent complications. With the early onset in life and the lack of curative treatment, a lifetime of monitoring is needed. Endoscopy is the golden standard to detect mucosal inflammation. This is however an invasive procedure and not suitable for frequent monitoring. The ideal monitoring test is non-invasive, simple to conduct, and detects (imminent) disease activity, so treatment can be timely optimized. The test should be suitable for remote monitoring and should measure doctor’s perspective on disase activity, but also take into account the patient’s perspective. Several non-invasive patient questionnaires to monitor disease activity have been developed, such as the Monitor IBD At Home (MIAH) score, mobile Health Index (mHI), the Manitoba IBD Index and IBD-control questionnaire. Diagnostic accuracy of symptom-based monitoring is insufficient. The Maastricht University Medical Center+ recently implemented QuantOn Cal (QOC) tests for patients to determine fecal calprotectin at home. It is yet unknown which patient questionnaire, combined with the QOC test, has the best diagnostic test accuracy for mucosal inflammation.

Objective: The main objective of this study is to determine the best remote monitoring tool for mucosal inflammation in adults patients with inflammatory bowel disease, relative to the golden standard endoscopy.

Study design: This is a cross-sectional cohort study. IBD patients are asked to fill out questions regarding disease activity (MIAH, mHI, Manitoba, IBD-control), perform one QOC test and collect one stool sample for routine laboratory calprotectin measurement, before the start of the bowel preparation for the ileocolonoscopy. During this ileocolonoscopy, endoscopic disease activity according to the SES-CD or MES will be determined.

Study population: Adult patients with an established diagnosis of Crohn’s disease or ulcerative colitis, scheduled for an ileocolonoscopy as part of routine care, are eligible.
Main study parameters/endpoints: The main study parameter is the diagnostic test accuracy of various patient reported scores (MIAH, mHI, Manitoba, IBD-control) in combination with the QOC test in detecting mucosal inflammation, using ileocolonoscopy as the golden standard.

Doel van het onderzoek

We hypothesize that the MIAH combined with the QOC and the mHI combined with the QOC will have the best diagnostic accuracy, and have comparable overall se/sp.
We hypothesize that the diagnostic accuracy of the Manitoba and IBD control is less, since these scores are focused more on patient's than on doctor's perspective of disease activity, and consequently less on mucosal inflammation.

Onderzoeksopzet

baseline, 1 week

Contactpersonen

Publiek

Maastricht University
Laura Janssen

0433884190

Wetenschappelijk

Maastricht University
Laura Janssen

0433884190

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Established diagnosis of CD or UC according to ECCO guidelines
- Scheduled for an ileocolonoscopy at the endoscopy ward of the MUMC+ (regardless of indication)
- Aged 18 years or older
- Smartphone with internet access (for use of QOC home test)

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Unclassified IBD
- Ileostomy, colostomy, ileoanal pouch anastomosis or ileorectal anastomosis
- Insufficient knowledge of Dutch language

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 nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	286
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:	08-03-2021
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	NL9313
Ander register	METC azM/UM : METC 20-085

Resultaten