Remote monitoring of IBD

No registrations found.

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

Summary

ID

NL-OMON21966

Source
NTR

Brief title
TBA

Health condition

Inflammatory bowel disease; Crohn's disease; ulcerative colitis

Sponsors and support

Primary sponsor: UM
Source(s) of monetary or material Support: UM

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

- Agreement between fecal calprotectin levels measured by QOC tests and by routine MUMC+ laboratory tests
- Association between the questions used in the various patient based disease activity scores and endoscopic disease activity

Study description

Background summary

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.

Study objective

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.

Study design

baseline, 1 week

Contacts

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Eligibility criteria

Inclusion criteria

- 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)

Exclusion criteria

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

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:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	286
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-03-2021
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	NL9313
Other	METC azM/UM : METC 20-085

Study results