Comparison of patient reported disease activity scores combined with calprotectin home tests for remote monitoring of IBD patients: a cross-sectional cohort study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON54092

Source
ToetsingOnline

Brief title
Remote monitoring of IBD.

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: disease activity score, IBD, intestinal inflammation, remote monitoring

Outcome measures

Primary outcome

The primary outcome is prediction of mucosal inflammation in daily clinical

practice, using the below listed PROMs (with and without FC home test),

relative to the gold standard ileocolonoscopy:

- MIAH

- Mobile health Index

- Manitoba IBD index

- IBD-control

- p-HBI / p-SCCAI

In addition, redeveloped and optimized PROMs are a primary endpoint.

Secondary outcome

- Prediction of mucosal inflammation in a strict trial setting using PROMs with

and without FC home test, relative to the gold standard ileocolonoscopy

- Agreement between fecal calprotectin levels measured by calprotectin home

tests and by routine laboratory tests in the participating centers

- Association between abdominal pain and histologic disease activity

- A validated profile of VOCs that predicts endoscopic and/or histological

disease activity in IBD

- The relation of oxylipins to IBD mucosal inflammation and the relation to VOCs

- Association between fatigue, persistent abdominal complaints and endoscopic and/or histological disease activity

- Association between anxiety and depression, persistent abdominal complaints and endoscopic and/or and histological disease activity

- Association between altered quality of life, medical consumption and work productivity in relation to persistent abdominal complaints and endoscopic disease activity.

Study description

Background summary

Crohn*s disease and ulcerative colitis are chronic inflammatory bowel diseases (IBD) with a heterogeneous disease course. 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 both doctor*s and patient*s perspective on disease activity. Several non-invasive patient reported disease activity scores have been developed, such as the Monitor IBD AT Home (MIAH) score, mobile Health Index (mHI), the Manitoba IBD Index, IBD-control questionnaire, patient based Harvey Bradshaw Index p-HBI) and patient based Simple Clinical Colitis Activity Score (p-SCCAI). Diagnostic accuaracy 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 reported score, combined with a fecal calprotectine home test, has the best diagnostic test accuracy for mucosal inflammation. In addition, it is hypothesized that the persistent inflammatory condition in IBD produces certain unique volatile organic compounds (VOCs) that appear in breath and feces during active inflammation, indicating the potential of these VOCs to serve as markers

for IBD disease monitoring. Furthermore, changes in VOCs profiles are expected to correlate with oxylipin levels in blood.

Study objective

The main objective of this study is to determine which PROM (with and without FC home test) is best for remote monitoring mucosal inflammation in IBD patients in daily clinical practice, relative to the gold standard ileocolonoscopy.
Additionally, we want to redevelop and thereby optimize PROMs (with and without FC home test) for screening for mucosal inflammation in IBD patients.

Secondary objectives:
- To determine which PROM (with and without FC home test) is best for remote monitoring of mucosal inflammation in IBD patients in a strict trial setting, relative to the gold standard ileocolonoscopy.
- To determine the correlation between the fecal calprotectin levels measured by QOC home tests and by the routine laboratory tests of the participating centers.
- To identify and validate a profile of volatile organic compounds in exhaled breath and/or feces that predicts histological disease activity in IBD.
- To investigate the relation of oxylipins in blood to IBD mucosal inflammation and the relation to VOCs
- To determine the association between abdominal pain and histologic disease activity
- To determine the association between fatigue, persistent abdominal complaints and endoscopic disease activity.
- To determine the association between anxiety and depression, persistent abdominal complaints and endoscopic disease activity.
- The determine the association between altered quality of life, medical consumption and work productivity in relation to persistent abdominal complaints and endoscopic disease activity.

Study design

This is a cross-sectional cohort study. Patients are asked to fill in questions regarding disease activity,(MIAH, mHI, Manitoba, IBD-control p-HBI/p-SCCAI) and disease related and overall wellbeing (abdominal pain (IBD-SSS), health consumption (MCQ), productivity and costs (PCQ), fatigue (MFI20), mental wellbeing (VSI, PHQ-9, GAD-7) and Quality of Life (QoL) (EQ-5D-5L), perform one calprotectin home 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.
The analysis of VOCs and , oxylipins and metabolic profiles will be performed in patients that are included at the MUMC+ only. These patients are asked to

visit the hospital one additional time to collect exhaled breath samples. Furthermore, these patients are asked to bring an additional fecal sample and,if patiens have IV access during endoscopy and provide consent, a blood sample will be taken from this IV.

Study burden and risks

Participation in this study means:
- Filling out questionnaires (142 questions) online, which takes time
- Performing one or two fecal home tests by the patient self; this brings no additional health risk
- Collecting one or two fecal sample and storing this in the fridge at home until taken to the hospital
- If a patient from the MUMC+ agrees to participate in the additional sub-study and thus to have their breath samples taken for the analysis of VOCs, patients are asked to pay an additional visit to the clinic to collect the breath samples. If these patients have IV access during the endoscopy and they provided consent, an additional blood sample will be taken from this IV.

No potential issues of concern or additional risks are associated with participation in this study.
Participation in this study is not associated with any direct benefit. A possible benefit of participating in this study is the chance to play a role in the improvement of non-invasive remote monitoring of IBD patients. Additionally, a possible benefit is decreasing the need for endoscopic evaluation of mucosal inflammation and thereby decreasing the risk of complications caused by this invasive procedure. Furthermore, if patients can be safely and accurately monitored remotely this can post a time benefit for both patients and health care professionals. The additional questions about IBS complaints could help to gain insight into abdominal complaints in IBD patients whenever inflammation is not immediately detected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Established diagnosis of CD or UC based on ECCO guidelines
- CD or UC patients scheduled for an ileocolonoscopy, or UC patients scheduled for an sigmoidoscopy at the endoscopy ward of one of the participating centers (regardless of indication)
- Aged 18 years or older
- Smartphone with internet access (for use of fecal calprotectin home test)

Exclusion criteria

- Unclassified IBD
- Ileostomy, colostomy, ileoanal pouch anastomosis or ileorectal anastomosis
- Isolated upper gastro-intestinal CD, or isolated peri-anal disease
- Insufficient knowledge of Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-06-2022
Enrollment:	400
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	05-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-02-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-02-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-08-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL75205.068.20