Trans-abdominal ultrasound as a point-of-care test for the assessment of disease activity in patients with ulcerative colitis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON42820

Source
ToetsingOnline

Brief title
UltraSound for ULceraticve colitis (USeFUL)

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colonoscopy, ulcerative colitis, ultrasonography

Outcome measures

Primary outcome

Candidate parameters for the ultrasound index:

colon wall thickness, colon wall layer stratification, mucosa thickness,

submucosa thickness, muscularis propria thickness, colon wall perfusion,

superior mesenteric artery (SMA) blood flow, inferior mesenteric artery (IMA)

blood flow, colon visibility, colon contents, disease extent (affected area),

haustra coli visibility, mesenteric lymphnodes,

Secondary outcome

other parameters:

endoscopic disease activity (UCEIS, Mayo), clinical disease activity (SCCAI,

Mayo), biochemical disease activity (inflammatory parameters), patient

satisfaction, examination costs.

Study description

Background summary

In recent years, it has been shown that mucosal healing is associated with better outcomes in patients with inflammatory bowel disease (IBD). However, repeated assessment of the mucosa currently requires multiple endoscopies which creates logistic and economic problems as well as a considerable burden for the patient. Therefore, alternative tools to assess luminal disease activity in IBD patients are needed. Chemical assays such as the measurement of faecal calprotectin and serum C-reactive protein, albumin and platelet counts have been evaluated but these test are hampered by significant errors and

unreliability. It has been reported that trans-abdominal ultrasound is useful for the detection and follow-up of patients with IBD and that this imaging technique can be applied to determine the extent and location of inflammation. However, only a few studies have been performed that compare trans-abdominal ultrasound with endoscopy for the assessment of mucosal disease activity and prospective studies in which treatment decisions are made based on ultrasound appearance are also limited. The aim of the proposed study is to develop and validate an ultrasound activity index for the assessment of mucosal disease activity in patients with ulcerative colitis (UC), compared to endoscopy as the reference (*gold*) standard. In a later phase, this activity index will be validated for the assessment of treatment effect.

Study objective

The primary objective of this study is to develop an ultrasound-based activity index with appropriate cut-off values that can be used as a point-of-care test for the assessment of mucosal disease activity in UC patients. Secondary objectives of this study are to assess the relative importance of individual ultrasound parameters and patient satisfaction. Lastly, a cost-benefit analysis will be performed.

Study design

Observational cross-sectional study. In the second phase the activity index will be validated prospectively by monitoring treatment effect (not described in this protocol).

Study burden and risks

Blood will be drawn once in order to measure various inflammatory markers as part of standard care. Patients will be subjected to two non-invasive trans-abdominal ultrasound examinations and one colonoscopy or sigmoïdoscopy. Only patients who need to undergo endoscopy in the frame of their usual care will be included. Trans-abdominal ultrasound is a safe procedure that uses high frequency sound waves for the visualization of internal organs. Another advantage of ultrasound is the fact that it is inexpensive compared to other techniques, such as endoscopy or Magnetic Resonance Imaging (MRI). Endoscopy is a relative safe procedure. The two most common complications of colonoscopy are bleeding and perforation (0,2 %, 0,1 %). Implementation of trans-abdominal ultra sound as a point-of-care test for the assessment of disease activity in UC patients may result in a reduced need for colonoscopy and MRI, thereby reducing costs and the burden for patients. Waiting times for MRI and colonoscopy are also long whereas ultrasound can be applied on a more regular basis. Treatment decisions based on ultrasound appearance can therefore be made *on the spot*, allowing for a point-of-care approach in these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histo-pathologically confirmed diagnosis of UC
- Quiescent disease, mild to moderate active disease or moderate to severe active disease according to the Montreal classification
- Needing a endoscopy with biopsies for evaluation of the disease

Exclusion criteria

- Pregnancy
- Age < 18years
- Chronic obstructive lung disease
- Acute coronary heart disease

- Ongoing gastroenteritis
- Previous colorectal surgery
- Obesity (BMI >30 kg/m²)
- Coagulation disorders
- Use of warfarins

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	06-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL54258.018.15