A new ultrasonographic scoring model for stricturing complications in Crohn*s Disease: elastography, contrast-enhanced and small intestinal contrast ultrasonography combined

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The primary objective of this study is to investigate if shear-wave elastography and contrast-enhanced ultrasonography can identify those patients most suitable fir an intervention (surgery or endoscopic balloon dilation) and those patients that...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON45764

Source
ToetsingOnline

Brief title
An ultrasonographic scoring model for stricturing Crohn's Disease

Condition

- Gastrointestinal stenosis and obstruction
- Autoimmune disorders

Synonym
Crohn's disease, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Grants

Intervention

Keyword: Crohn, stricture, ultrasound

Outcome measures

Primary outcome

Difference of parameters between intervention vs no intervention group:

* Speed of velocity of shear-wave (m/s)

* Mean transit time of intravascular contrast (second)

* Time to peak (second)

* Blood volume per tissue (mL/100 mL tissue)

* Blood flow (meter per second)

Secondary outcome

* Location of bowel wall thickening (small intestine, terminal ileum,

ascendens, transversum, descendens, sigmoid, rectum)

* Wall layer thickness of mucosa, submucosa, muscularis propria, serosa (mm)

* Length of affected intestine (cm)

* Bowel wall width (mm)

* Preserved bowel wall stratification (yes/no)

* Preserved haustration (yes/no)

* Loss of bowel motility (yes/no)

* Prestenotic dilation (yes/no)

* Minimal lumen width (mm)

* Fatty wrapping (yes/no)

* Abscesses (yes/no)

* Fistula (yes/no)

* Enlarged lymph nodes (yes/no)

* Colour Doppler Activtiy (yes/no)

* Location of Doppler activity (within the bowel wall/outside of bowel wall)

* Response of medical treatment within 52 weeks defined as:

o Clinical improvement defined as a decrease in CDAI*100 points from baseline

AND/OR

o Clinical remission defined as CDAI<150 AND/OR

o Biochemical remission defined as CRP*5.0 mg/L and fecal calprotectin<250 mg/g

* Identification of stenosis with B-mode

* Identification of stenosis with SICUS

* Clinical deterioration within 52 weeks defined as a CDAI*220 and an increase

in CDAI*100 points

* Correlation of SWE and CEUS with other biochemical parameters at baseline,

week 12, 26 and 52 (Leukocyte count (109/L), Haemoglobin (mmol/L), Platelet

count (109/L), Erythrocyte count (1012/L), Albumin (g/L), Fecal calprotectin

(µg/g))

* Change of ultrasonographic parameters in the response group at baseline and

at 26 and 52 weeks.

* Decrease in biochemical parameters within 52 weeks (CRP>5 mg/L and fecal

calprotectin >50 mg/g))

Histological parameters:

Histologically, mucosa, submucosa, muscularis propria and serosa will be examined on the following: cryptitis, ulcerations, crypt abscessess, occurrence of neutrophilic, lymphocytic en eosinophilic cells, extent of fibrosis, muscle layer width and expansion of muscle layer, collagen deposition, fibroblast proliferation, adipose tissue proliferation

Study description

Background summary

In the course of Crohn*s disease (CD) stricturing is a regular occurring phenomenon. In 20% of patients strictures develop within 10 years of disease onset with half of these patients facing surgery. Both inflammation and fibrosis contribute to development of strictures in CD. However, where strictures of mainly fibrotic origin are considered as end-stage of disease and surgery is often inevitable, inflammatory strictures might be well treated medically. Therefore it is of major importance to differentiate between inflammatory and fibrotic strictures and adapt treatment accordingly. Currently strictures are often diagnosed at endoscopy or by magnetic resonance enterography (MRE) and subsequent treatment is often based on clinical and biochemical disease pattern. According to previous studies, ultrasound correlates with endoscopy, magnetic resonance imaging (MRI) and computed tomography (CT) in disease assessment of CD. Furthermore, ultrasound might be promising in monitoring stricturing disease. Several ultrasonographic modalities, such as contrast-enhanced ultrasound (CEUS), elastography and small intestine contrast ultrasonography (SICUS) have been developed and investigated and are promising in diagnosing and characterizing strictures. A combination of these modalities might improve assessment of strictures. Therefore we postulate that the combination of several ultrasonographic modalities will reflect strictures in CD and consequently of additive value in the assessment of stricturing CD.

Study objective

The primary objective of this study is to investigate if shear-wave elastography and contrast-enhanced ultrasonography can identify those patients most suitable fir an intervention (surgery or endoscopic balloon dilation) and those patients that should receive anti-inflammatory treatment. SWE and CEUS

data of the stricture(s) in the group that do not receive an intervention within one year will be compared with SWE and CEUS data of the intervention group.

* What ultrasonographic parameters could be used to identify patients most suitable for an intervention and what patients might benefit most from anti-inflammatory medical treatment?
* Do CEUS and elastography correlate with each other?
* Comparing histology of resection specimen after surgery with ultrasonographic data prior to surgery
* Development of a stricture scoring tool using ultrasonographic variables

Study design

Single-center, cross-sectional observational study

When stricturing disease is diagnosed patients will be discussed in a multidisciplinary meeting and subsequent treatment will be planned. After signed informed consent patients will be included. Clinical disease activity scores and biochemical parameters will be collected. Furthermore, an intestinal ultrasonography is planned. At the day of ultrasonographic analysis the participant is asked to fast for six hours prior to the ingestion of oral contrast. Then SICUS is performed and will take between one and two hours. Subsequently, intravascular contrast is injected and CEUS is performed on the region of interest (ROI), which will be the stricture(s). Then SWE is performed on the earlier identified stricture(s). The combined procedure will take between one and two hours in total.

The group of patients allocated to medical treatment will be followed for 52 weeks. After 12 and 26 weeks clinical disease activity scores and biochemical parameters will be collected. When patients do not undergo surgery within the 52 weeks of follow-up clinical disease activity scores and biochemical parameters will be measured and collected. Furthermore, a B-mode ultrasonographic exam will be iterated at week 26 and 52. No surgery within 52 weeks will be classified as successful medical treatment.

All patients receiving endoscopic balloon dilation or surgery within 52 weeks of baseline ultrasonography will be in the intervention group. In case of surgery, if the previous ultrasonographic examination is older than 8 weeks patients will receive a new ultrasonographic examination. In case of resection, the resection specimen is collected and will be transferred to the pathologist.

The pathologist will secure the specimen, identify the stricture and its length. Then, the specimen is prepared macroscopically following a local protocol. At last, the specimen will be stored by the pathologist. Subsequently, an IBD-experienced pathologist (AM) will assess the specimens histologically on mainly inflammatory-predominant and fibrosis-predominant

features. Intervention within 52 weeks of baseline is another endpoint of this protocol.

Study burden and risks

This study is not involved with major risks. For intravascular contrast the most serious risk is anaphylaxis, although reported in less than 1:10.000 patients. Other minor side-effects, such as headache and nausea, are reported in a small number of patients. For oral contrast no major or minor side-effects are reported. However, diarrhoea could be a plausible side-effect and will therefore be monitored. Other ultrasonographic modalities do not come with notable risks.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Histological confirmed Crohn*s Disease
* Age * 18 year
* Stricturing disease diagnosed by endoscopy and/or radiologic imaging
* Receive medical treatment, endoscopic dilation or surgery

Exclusion criteria

* * Time between ultrasonography start of medical treatment and baseline ultrasonography and interventional treatment exceeding 8 weeksexceeding two weeks
* Endoscopic balloon dilation prior to baseline ultrasonography
* Pregnancy
* Chronic obstructive lung disease
* Acute coronary heart disease
* Clinically unstable heart disease
* Previous allergic reaction to Sonovue or to its components
* Ongoing gastroenteritis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Generic name:	Ultrasonography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-02-2019
Application type:	First submission
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	NL67230.018.18