Diagnostic Accuracy of Ultrasound Indices in pediatric IBD

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To determine the accuracy of US for detecting disease activity in paediatric patients with IBD and to develop an easy-to-use and accurate US-activity index that can accelerate and improve clinical management by reducing the need for gastrointestinal...

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

Summary

ID

NL-OMON49470

Source ToetsingOnline

Brief title RAINBOW-1

Condition

• Gastrointestinal inflammatory conditions

Synonym

chronic inflammation of the bowel, Inflammatory Bowel Disease

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Diagnostic accuracy, Inflammatory Bowel Disease, Pediatric, Ultrasound

Outcome measures

Primary outcome

Diagnostic test accuracy of ultrasound as compared to golden standard imaging

(ileocolonoscopy or MRE).

Secondary outcome

Interobserver variability of US.

Study description

Background summary

Children with Inflammatory Bowel Disease (IBD) are exposed to a high number of invasive diagnostic procedures (most frequently gastrointestinal endoscopies and Magnetic Resonance Enterography (MRE)) during their lives. Most children experience important anxiety during these procedures. In addition, gastrointestinal endoscopies are more invasive in children compared to adults due to the need for nasogastric tubes for bowel cleansing and general anesthesia. To reduce this burden, moving towards a future with more accurate non-invasive diagnostics is needed. Ultrasound (US) is a non-invasive, fast and inexpensive way of imaging the bowel. However, little is known about its accuracy in the paediatric population.

Study objective

To determine the accuracy of US for detecting disease activity in paediatric patients with IBD and to develop an easy-to-use and accurate US-activity index that can accelerate and improve clinical management by reducing the need for gastrointestinal endoscopies and MRE.

Secondary objective: to assess the inter- and intra-observer variability of US.

Study design

A prospective observational study in paediatric patients with (suspicion of) IBD. US will be performed concomitant with standard care ileocolonoscopy and MRE. Accuracy of different US features (e.g. wall thickness, vascularisation, lymph nodes, wall layer stratification) will be assessed per segment using ileocolonoscopy as reference standard for large bowel and MRE for small bowel. Subsequently an US-activity index based on the individual US parameters will be composed using regression analysis. In addition inter- and intraobserver variability of individual US features of the bowel and of the newly developed US activity index will be determined.

Study burden and risks

Ultrasound is a safe, fast and non-invasive way of imaging, hence the extent of the burden of participating is limited. There will be no direct benefits of participating. However after completion of this study, patients might benefit from the possibility to be monitored more accurately in a non-invasive manner.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adolescents (12-15 years) Adolescents (16-17 years)

3 - Diagnostic Accuracy of Ultrasound Indices in pediatric IBD 13-05-2025

Children (2-11 years)

Inclusion criteria

- Age 6-18
- Diagnosed with IBD or suspicion of IBD
- Undergoing MRE and/or endoscopy for routine care

Exclusion criteria

- Ongoing gastroenteritis
- Pregnancy
- Previous intestinal surgery
- Histologically proven CMV infection

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):	12-08-2019
Enrollment:	124
Туре:	Actual

Ethics review

Approved WMO	
Date:	19-06-2019
Application type:	First submission

4 - Diagnostic Accuracy of Ultrasound Indices in pediatric IBD 13-05-2025

Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2022
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 CCMO ID NL67729.018.18