

The clinical value of Point-of-Care Ultrasound in children with Crohn*s Disease

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To determine the clinical value of ultrasound, in addition to other non-invasive parameters of disease activity in children aged 3-18 with Crohn*s Disease.

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

Summary

ID

NL-OMON49127

Source

ToetsingOnline

Brief title

RAINBOW-2

Condition

- Gastrointestinal inflammatory conditions

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: Ministerie van OC&W

Intervention

Keyword: Children, Crohn's Disease, Disease Monitoring, Ultrasound

Outcome measures

Primary outcome

- Proportion of patients in whom POCUS led to a more severe classification of disease activity than faecal calprotectin.
- Proportion of patients in whom POCUS would have altered choice for therapy

Secondary outcome

- Prognostic value of US for predicting a flare in the future

Study description

Background summary

Children with Crohn's Disease need to be monitored closely in order to detect and treat disease flare-ups in time. Pediatric gastroenterologists prefer to use non-invasive tests, such as inflammatory markers in blood and faeces, as much as possible, and to minimize the need for invasive procedures, such as ileo-colonoscopies. However, these inflammatory markers are often inconclusive. Using point-of-care ultrasound (POCUS) in addition to the currently used non-invasive test in these children could improve clinical care.

Study objective

To determine the clinical value of ultrasound, in addition to other non-invasive parameters of disease activity in children aged 3-18 with Crohn's Disease.

Study design

A single centre observational study. POCUS will be performed in all children (aged 0-18) diagnosed with Crohn's Disease, visiting the outpatient clinic, and in whom inflammatory markers of disease activity will be determined for standard care. POCUS results and inflammatory markers results will be categorized in three categories: remission/ mild activity/ moderate-severe activity. Impact of the POCUS on choosing treatment will be determined and

agreement between-, and additive value of POCUS and inflammatory markers results will be assessed

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. The children will spend 30 minutes longer in the outpatient department.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Diagnosed with Crohn's Disease
- Age 3-18 year

Exclusion criteria

- Proven gastro-enteritis
- Pregnant at time of examination

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-06-2020

Enrollment: 76

Type: Actual

Ethics review

Approved WMO

Date: 29-04-2020

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	NL72606.018.20