Early prediction of treatment response in children with Inflammatory Bowel Disease with Intestinal Ultrasound

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To assess the early predictive value of IUS for therapy response in children with IBD (new onset or known IBD).

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

Summary

ID

NL-OMON51551

Source
ToetsingOnline

Brief title
RAINBOW-3

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: ECCO grant

Intervention

Keyword: Inflammatory Bowel Disease, Pediatric, Treatment response, Ultrasound

Outcome measures

Primary outcome

To assess the early predictive value of IUS at week 6 for therapy response

after 3 months in children with newly onset IBD starting therapy and children

with known IBD starting on remission induction therapy.

Secondary outcome

1. Predictive value of IUS at week 2 for treatment response at week 13.

2. To assess the difference in change of IUS parameters between different types

of remission induction therapy and types of IBD (CD versus UC).

3. Predictive value of transmural healing at week 13 as assessed by IUS for

remission at week 52.

Study description

Background summary

Choosing the right treatment for children with Inflammatory Bowel Disease (IBD) in the early stages of disease is key to prevent disease progression and to alter disease course. Intestinal Ultrasound (IUS) is a promising non-invasive biomarker for IBD whose potential for early prediction of treatment response has not been explored.

Study objective

To assess the early predictive value of IUS for therapy response in children with IBD (new onset or known IBD).

Study design

Prospective observational study. Children with IBD starting on remission

induction therapy will undergo an IUS at baseline (T0). In those with visible abnormalities, IUS will be repeated at 2 weeks (T1), 6 weeks (T2) and 13 weeks (T3). Response to therapy will also be determined at T3

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 with a new non-invasive biomarker which will help to predict the treatment response in an early stage.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Age 3-18y
Newly onset IBD or flare IBD
Starting new remission induction therapy

Exclusion criteria

No visible abnormalities on baseline IUS
Infectious gastroenteritis
Acute severe ulcerative colitis
Surgery as remission induction therapy
Previous intestinal surgery
Pregnancy

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):	17-11-2022
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2022
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	NL81827.018.22