Faecal Metabolomics and Microbiota as Non-Invasive Biomarkers for Disease Activity and to Predict Treatment Response in Paediatric Inflammatory Bowel Disease

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

Summary

ID

NL-OMON55240

Source
ToetsingOnline

Brief title
Biomarkers for Disease Activity and Therapy Response in paediatric IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Maag Lever Darm Stichting

Intervention

Keyword: Inflammatory bowel disease, Metabolome, Microbiome, Therapy response

Outcome measures

Primary outcome

We expect to identify IBD-specific microbial and metabolic profiles associated with disease activity, enabling development of clinical decision-making algorithms for earlier detection of paediatric IBD in an intention-to-diagnose population. This would allow for personalized and tailored monitoring of disease activity, timely recognition of exacerbations and prediction of treatment response, improving IBD care.

Secondary outcome

Not applicable.

Study description

Background summary

Inflammatory Bowel Disease (IBD) is a group of disorders of the gastro-intestinal tract, characterized by chronic relapsing intestinal inflammation. The gold standard to detect and monitor IBD is endoscopic assessment which is costly and invasive, illustrating the need for development of novel non-invasive diagnostic biomarkers. Previous studies have demonstrated the potential of microbiota and intestinal metabolomics to serve as biomarkers for monitoring disease activity and to predict therapy response in paediatric IBD patients. However, these studies were characterized by a small sample size and validation in larger cohort of paediatric IBD patients is needed.

Study objective

It is aimed to develop fecal microbiota-metabolomics based algorithms for diagnostics, monitoring and predicting therapy response in IBD which can be applied in daily clinical practice and to identify predictive factors for outcome and treatment response or non-response.

Study design

The proposed study will be conducted in a prospective multicenter study design with a longitudinal follow-up, starting mid-August 2020 for a duration of 36 months.

Study burden and risks

No blood sampling or endoscopy for this study will be performed outside routine blood samplings and endoscopy. The patient*s risk of participation in this proposed study is very low. Potential risks of a blood sample drawn are the induction of temporary discomfort, bruising, swelling and/or in rare circumstances, infection at the needle site. Potential risk of additional biopsy taken from the digestive tract is the very small risk of a perforation or bleeding (risk < 0.1%). Biopsies from the digestive tract will only be taken during regular patient care endoscopic procedure involving biopsy taking. The burden is considered minimal. Since disease phenotype, course of the disease and benefits and risks of treatment differ between children and adults, this study cannot be performed in adult patients.

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

- Age of 4-17 years
- New patients with a suspicion of IBD or patients with gastrointestinal symptoms who undergo diagnostic work-up (including clinical, laboratory and faecal markers but not necessarily endoscopy) to exclude IBD may be recruited. If a diagnosis is not confirmed after the investigations are complete they will not be followed up any further but any specimens and clinical information can be retained as controls
- Written informed consent
- Patients have not started IBD treatment yet

Exclusion criteria

- Use of antibiotics or probiotics in the last 3 months prior to inclusion
- Use of immunosuppressive therapy prior to the study
- Patients diagnosed with immunocompromised disease (any of various diseases that suppress the immune system)
- Inability to read and understand the patient and family information sheets (for example insufficient knowledge of national language, where no health advocate of family member is available to translate and ensure full understanding of the study)
- Informed consent of patient and/or parents has not been obtained when required

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):	28-10-2020
Enrollment:	185
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-12-2021
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	NL74186.029.20