Predictive biomarkers for inflammatory bowel disease-associated dysplasia

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To collect biomaterials (peripheral blood, DNA, serum, faeces and intestinal biopsies from IBD patients with dysplastic lesions in the colon to allow research into the immunological pathways leading to dysplasia development.

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

Summary

ID

NL-OMON51848

Source
ToetsingOnline

Brief title
Dysplasia-IBD

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Cancer, Dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dysplasia, Inflammatory bowel disease, Microbiome

Outcome measures

Primary outcome

Identification of mucosal immune populations and the microbiome in biopsies taken from patients with aIBD with and without dysplasia, and with and without colitis-associated cancer.

Secondary outcome

Determination of patients* genotype (including whole genome methylome and transcriptome) associated with mucosal immunotype and microbiome in relationship to the presence of dysplasia/cancer.

Determination of luminal microbiome (in biopsies and faeces) associated with mucosal immunotype and microbiome in relationship to the presence of dysplasia/cancer

Determination of serum cytokines and chemokines associated with mucosal immunotype and microbiome in relationship to the presence of dysplasia/cancer

Study description

Background summary

One of the most severe complications of UC is the development of colorectal cancer (CRC). The incidence of CRC in patients with UC is higher compared to the healthy population, and in subgroups of UC patients the incidence is up to 7 times higher. The etiology of CRC in UC patients (colitis-associated cancer,

CAC) is different from that of patients with sporadic CRC, yet the mechanisms have not been fully elucidated.

Understanding the complex etiology of CAC is highly relevant and a large unmet clinical need. Understanding the disease is necessary to prevent CAC, to detect CAC at an early stage, and to understand which patients are most at risk. This group should undergo more frequent colonoscopy surveillance to detect lesions before they develop into cancer.

CAC arises from a complex interplay between genetic, environmental (microbiome) and immune-driven triggers/defects, and is even more complicated by the use of different anti-inflammatory drugs. One of the problems of investigating CAC and forcing breakthroughs in this field that lacks innovation, is that emerging novel concepts (in for example the microbiome or immune-driven triggers for CAC) are difficult to test because of the lack of patient*s materials from a population in which prospective sampling is typically extremely time-consuming.

Study objective

To collect biomaterials (peripheral blood, DNA, serum, faeces and intestinal biopsies from IBD patients with dysplastic lesions in the colon to allow research into the immunological pathways leading to dysplasia development.

Study design

This is a study based on a systems biology approach. Individual IBD patients with undergoing consecutive routine care surveillance endoscopies will be studied. Patients will only undergo colonoscopies if that is part of their routine care.
In parallel to the collection of patients* phenotypic data and detailed information on response to various treatments, mucosal biopsies from normal and/or potentially dysplastic tissues or cancer will be collected and analysed for cytokines and chemokines, cell types and mucosa associated microbiome. Moreover, blood, serum and faeces will be stored for analysis of the genotype (including whole genome methylome and transcriptome) the serum cytokine/chemokine profile and the *luminal* faecal microbiome/metabolome.

Study burden and risks

Peripheral blood is sampled with a negligible risk and low burden.

Endoscopic biopsies taken during colonoscopy include a minimal risk of complications, mainly bleeding or perforation (< 1: 10,000). In case complication occurs, endoscopic treatment (hemostasis/clipping) is effective in most cases. Rarely, hospital admission with/without surgical intervention,

antibiotic therapy and/or blood transfusion can be required.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All adult patients (>=18 y/o) with a diagnosis of IBD undergoing surveillance colonoscopies can be enrolled after giving written informed consent to enrollment.

Exclusion criteria

- Ongoing malignancy (other than CRC).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2023
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	19-09-2022
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	NL79540.018.22