

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	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

### Public

Amsterdam UMC

Meibergdreef 9  
Amsterdam 1105BK  
NL

### Scientific

Amsterdam UMC

Meibergdreef 9  
Amsterdam 1105BK  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All adult patients ( $\geq 18$  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

CCMO

### ID

NL79540.018.22