# Determining the safety and feasibility of optical coherence tomography and near infrared fluorescence: a prospective pilot intervention study

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- Primary: Determine safety and feasibility of immuno-OCT in vivo imaging with the tracer Bevacizumab-800CW. - Secondary: Validate the immuno-OCT endoscopy system based on:o Fluorescence molecular endoscopy;o Ex vivo fluorescence imaging; o Ex vivo...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal neoplasms malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56591

**Source**
ToetsingOnline

**Brief title**
Safety and feasibility of immuno-OCT (DETOUR)

### Condition

- Gastrointestinal neoplasms malignant and unspecified

**Synonym**
Barret's esophagus, coloncarcinoma, dysplasia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** NWO,Glycanscan

## Intervention

**Keyword:** Endoscopy, fluorescence, near-infrared, optical coherence tomography

## Outcome measures

### Primary outcome

- Safety:

o Number of Adverse Device-related Events (ADEs) and Serious Adverse

Device-related Events (SADEs).

- Feasibility:

o Feasibility to acquire images with the immuno-OCT endoscope and to interpret

the resulting images and results. This will not be statistical analyzed.

### Secondary outcome

- Validation of the immuno-OCT endoscopy system based on:

o Fluorescence molecular endoscopy;

o Ex vivo fluorescence imaging;

o Ex vivo immuno-OCT imaging;

o Immunohistochemistry.

# Study description

### Background summary

To improve detection of premalignant lesions in the gastrointestinal tract (the rectum and the esophagus) there is a need for better endoscopic visualization and the ability for targeted biopsies. The University Medical Center Groningen (UMCG) developed a fluorescent tracer by labelling the VEGF-A*targeting humanized monoclonal antibody bevacizumab, currently used in anti-cancer therapy, with the fluorescent dye IRDye800CW (Bevacizumab-800CW). In several

phase I studies and phase II studies, either completed or currently running, in the UMCG, the use of VEGF-A-guided near-infrared (NIR) fluorescence molecular endoscopy (FME) in combination with high-definition white light endoscopy (HD-WLE) shows an improved detection rate of early premalignant lesions. In this study the safety and feasibility of a next generation imaging system will be tested. This system uses immune optical coherence tomography (immuno-OCT) and near infrared fluorescence (NIRF) with the targeted tracer (Bevacizumab-800CW) for improvement of the detection of dysplastic lesions in Barret*s esophagus (BE) and colorectal polyp detection. The system provides more depth information and can eventually be used without the guidance of the regular endoscopy system.

**Study objective**

- Primary: Determine safety and feasibility of immuno-OCT in vivo imaging with the tracer Bevacizumab-800CW.
- Secondary: Validate the immuno-OCT endoscopy system based on:
o Fluorescence molecular endoscopy;
o Ex vivo fluorescence imaging;
o Ex vivo immuno-OCT imaging;
o Immunohistochemistry.

**Study design**

The current study is a non-randomized, non-blinded, prospective and single-center feasibility and safety study. Patients in the UMCG known with BE or colorectal polyps and scheduled for endoscopic resection will be included in this study. The primary endpoint of this study is the determination of the safety and feasibility of the immuno-OCT system.

**Intervention**

Patients scheduled for an endoscopic resection and eligible for this study will receive information about this study through the phone or when visiting the out-patient clinic. When patients are willing to participate in the study they will receive an intravenous administration of Bevacizumab-800CW below therapeutic dosage, two to four days before the endoscopy procedure or they will receive topical administration of bevacizumab-800CW. Vital signs will be measured before, directly after and ten minutes after injection. The endoscopy procedure will consist of three phases. First the patient will receive standard clinical care with HD-WLE in which all visible suspicious and malignant lesions will be identified. In the next phase, FME will be applied and suspicious fluorescent areas will be inspected by HD-WLE. Thirdly, immuno-OCT will be applied. Biopsies will be taken to allow ex vivo correlation. The complete procedure will take an extra 15 - 25 minutes compared to regular care. During the procedure and measurements videos will be recorded which will be used for

further analysis. During the intervention the patient is under sedation. If a patient with esophageal lesions is included in the topical administration cohort, phase 2 and 3 will be performed immediately after application of the tracer (using a spraying catheter) and following incubation (5 minutes) and rinsing off the excess tracer with water. The concentration per cm2 will be controllable and results will therefore be comparable.

**Study burden and risks**

Time investment
Compared to standard care, one extra visit to the UMCG of about 20 minutes is needed when the patient receives IV administration. Regular procedure time is about 1 hour and will take 15 - 25 minutes longer due to our study.

Risks
The administration risks of Bevacizumab-800CW are reported in the Investigational Medicinal Product Dossier (version 6.0). The intravenous injection and the use of a cannula are known to carry a small risk of infection and hematoma. No adverse events were reported from previous administrations with Bevacizumab-800CW with more than 235 patients included. However, injection of Bevacizumab-800CW could induce an allergic reaction or hypertension. Due to fluorescence imaging and immuno-OCT, the endoscopy will be prolonged for 15 - 25 minutes. As the fiber of FME can be inserted through the working channel of the HD-WL endoscope, the risks of fluorescence imaging are comparable to HD-WL endoscopy. The fiber of immuno-OCT can be inserted in a similar way to the regular endoscope also minimizing the risks. The biopsy procedure may cause some bleeding which can often be treated by the gastroenterologist.

Benefit
There is no direct diagnostic or treatment benefit for the patients as all procedures are following standard clinical guidance. No decisions according to clinical care will be based on study results.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

• Indication for a therapeutic endoscopy procedure (EMR or ESD);
• Age >= 18;
• Written informed consent.

## Exclusion criteria

• Patients younger than 18 years old;
• Submucosal and invasive EAC or CRC;
• Radiation therapy for esophageal or colorectal cancer;
• History of infusion reactions to Bevacizumab or other monoclonal antibodies;
• Chemotherapy, immunotherapy or surgery 28 days before administration of the tracer;
• Non-adjustable hypertension;
• Medical or psychiatric conditions that compromise the patient*s ability to give informed consent;
• Pregnancy or breast feeding; a negative pregnancy test must be available for women of childbearing potential.

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2023 |
| Enrollment: | 15 |
| Type: | Anticipated |

## Medical products/devices used

| | |
|---|---|
| Generic name: | capsule endoscope OCT-NIRF system |
| Registration: | No |

# Ethics review

Approved WMO

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|---|---|
| Date: | 22-01-2024 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 |
| --- | --- |
| ClinicalTrials.gov | NCT06008522 |
| CCMO | NL82956.042.23 |