

Measurement of oxidation reduction potential in the colon using an ingestible sensor in patients with ulcerative colitis (UC) and colorectal cancer (CRC)

Published: 11-03-2025

Last updated: 25-03-2025

Measurement of intestinal oxidation-reduction potential using a smart sensing ingestible and its relation to active UC and CRC.

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

Summary

ID

NL-OMON57338

Source

ToetsingOnline

Brief title

SPIRIT

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym

', 'colon cancer', 'colorectal carcinoma', 'ulcerative colitis'

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting IMEC Nederland

Intervention

Keyword: colorectal carcinoma, oxidation reduction potential, sensor, ulcerative colitis

Outcome measures

Primary outcome

- Measurement of ORP profile in the colon using the GISMO GEN1 System in patients with UC or CRC before and after treatment.
- To relate intestinal ORP profile in the colon to known tumor location or area of inflammation, for respectively CRC and UC.
- To compare intestinal ORP and pH profiles before and after medical treatment or surgical resection for respectively UC and CRC.
- To relate intestinal ORP profile to measures of disease activity in UC, including fecal calprotectin (FC).
- To compare intestinal ORP and pH profiles of UC and CRC patients to those of healthy controls.
- To continue assessment of the feasibility of the GISMO GEN1 System in humans with GI tract related disorders by studying the ingestible transit time, data coverage, participant experience, and serious adverse events (if applicable).

Secondary outcome

NA

Study description

Background summary

The gold standard diagnostic tool for inflammatory bowel disease (IBD) and colorectal carcinoma (CRC) is endoscopy, which can be burdensome for patients. The future of IBD care demands novel, minimally invasive biomarkers for personalized care and CRC screening programs could greatly benefit from new minimally invasive diagnostic tools. Oxidative stress plays a significant role in the progression of gut inflammation and colorectal cancer. Using an ingestible sensor ingestible, we aim to measure oxidation-reduction potential (ORP) directly in the gut. We hypothesize that ORP levels are elevated in patients with active ulcerative colitis (UC) and CRC before treatment, compared to after treatment.

Study objective

Measurement of intestinal oxidation-reduction potential using a smart sensing ingestible and its relation to active UC and CRC.

Study design

Observational study with invasive measurements

Study burden and risks

Risk associated with participation are deemed low. Medical or surgical treatment is not altered in any way. Patients with UC will receive an additional IUS. The GISMO GEN1 ingestible device (size 21.8 mm x 7.64 mm) is an investigational tool deemed safe for human use in clinical settings, with risks detailed in the IMDD. Device exit will be tracked via the temperature sensor of the ingestible sensor. If exit is not confirmed after 14 days, an abdominal X-ray will confirm whether the device is still in the gastrointestinal tract. If visible on the abdominal X-ray, a medical specialist will determine further action, which may include laxatives or surgery, with costs covered by the research team. If abdominal X-ray examination is necessary, the participant may experience a maximum radiation exposure of 0.10 mSv. Participant burden is low; time investment including study visits, device checks and questionnaire is estimated around 4 hours in total. Main burden is expected to be the continuous wearing of the base device as long as the ingestible sensor remains in the body.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- age $\geq$ 18 years
 - diagnosed with colorectal cancer and planned for surgical tumour resection
- OR
- diagnosed with ulcerative colitis, with active inflammation as determined by increased bowel wall thickness on intestinal ultrasound

Exclusion criteria

- BMI $>$ 30 kg/m²
- Known obstruction, stricture or stenosis in the gastrointestinal tract not attributable to current inflammation or tumour, potentially blocking ingestible passage. Determined as per discretion of gastroenterologist/oncologist using standard procedural clinical diagnostic or imaging techniques.
- Pregnant, lactating or trying to get pregnant
- Pacemaker or other implantable electronic devices

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2025

Enrollment: 10

Type: Anticipated

Medical products/devices used

Generic name: GISMO GEN1 System

Registration: No

Ethics review

Approved WMO

Date: 11-03-2025

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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

NL88151.091.24