Using Diffuse Reflectance Spectroscopy Probes to conduct Optical Measurements during Surgery for Colorectal Cancer

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To assess the practical usability of our DRS probes for the detection of positive resection margins in colorectal cancer surgery - specifically whether they can be used in the confined surgical workfield in the lower pelvis - as well as the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON57332

Source
ToetsingOnline

Brief title
DRS for In Vivo Margin Assessment in CRC

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
cancer of the bowel, cancer of the rectum, colon cancer, Colorectal Cancer, rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: NKI

Intervention

Keyword: DRS, LARC, LRRC, Optical

Outcome measures

Primary outcome

The first outcome of the study will be the usability of the two probes,

assessed using an adapted SUS-score form.

Secondary outcome

The second outcome will be the predictive value of the selected DRS probe used

in conjunction with our algorithm to determine a positive resection margin

(defined as tumor within 1 mm of the resection edge).

Study description

Background summary

Differences in optical characteristics between malignant and benign tissue allow for the discrimination between these tissue types. By performing Diffuse Reflectance Spectroscopy (DRS) measurements at the planned resection plane during surgery for colorectal cancer, a surgeon could better plan the most optimal dissection plane, preventing a positive surgical margin. Lowering the incidence of positive resection margins increases disease-free survival and cancer-related survival. To use this technique in vivo during surgery for colorectal cancers, several probes have been developed in-house. Because of the limited space in the lower pelvis, the rigid pen-like Iris probe could maximize the area of the rectum that can be reached. In contrast, the smaller drop-in probe may make it easier to achieve optimal tissue contact in the deep pelvis and to aim the probe tip precisely. In the first part of this study, we aim to select the most suitable probe. In the second part, we will determine the accuracy of the selected probe in rectal surgery for determining positive resection margins.

Study objective

To assess the practical usability of our DRS probes for the detection of positive resection margins in colorectal cancer surgery - specifically whether

they can be used in the confined surgical workfield in the lower pelvis - as well as the predictive properties for estimating malignancy at the site of measurement.

Study design

During open resections of the rectum, after the TME plane has been developed but before the transection of the rectum, DRS measurements will be taken. For patients undergoing surgery for advanced colon cancer, pelvic recurrence of rectal cancer or HIPEC procedure, the measurements will be performed when the area of tumour tissue is approached. The study is divided in two distinct phases. In the first phase, we will test 2 designs of the optical probe: a blunt tip handheld pen-like probe (Iris probe) and a blunt tip *drop-in* probe. The most suitable and intuitive optical probe will be selected, based on the SUS score. To this end, patients will be spread across two groups, corresponding with the two different probes to be tested. Measurements of the first group of 9 patients will be obtained using the sterile, blunt tip, hand-held DRS Iris probe as described in study N19BOR. Measurements of the second group of 9 patients will be obtained using a sterile, blunt tip, drop-in DRS probe as described in study N20DPP. The Iris probe has one efferent and six afferent integrated optical fibres, which will be brought in contact with the surface of the resection plane. The drop-in probe has one efferent and one afferent fibre. The measured site will be marked peroperatively with sutures or clips, which will be replaced by ink marking before pathology analysis. At the end of the first phase, the most suitable and intuitive DRS probe will be selected by assessing the SUS score of the surgeons. With this probe we will continue the second phase of the study, aimed to determine the accuracy of this probe to predict a tumor positive resection margin. The obtained DRS spectra will be analysed using our machine learning algorithm, trained on earlier measurements on ex vivo specimens. We expect that we do not need to train a new algoritm, as we have extensive experience that ex vivo measurments are comparable to in vivo tissue measurments with regard to DRS. For validation we will use the gold standard pathology results on resection margin status.

Study burden and risks

No significant risks are expected; maximum of 5 minutes added to operation time.

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

Adult (eighteen years or older)
written informed consent
proven colorectal carcinoma
undergoing open surgical resection of tumour (including advanced colorectal primary tumour, colorectal pelvic recurrence (LRRC)) and peritoneal disease (HIPEC)

Exclusion criteria

Suspected oversensitivity to light; e.g. patient who has had photodynamic therapy
Use of intravenous fluorescent agents in the area to be measured

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	74
Type:	Anticipated

Medical products/devices used

Generic name:	Optical probe
Registration:	No

Ethics review

Approved WMO

Date:	28-02-2025
Application type:	First submission
Review commission:	METC NedMec

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	NL86549.041.24