In vivo identification of rectum and colon carcinoma during surgery using optical spectroscopy techniques

Published: 23-07-2014
Last updated: 15-05-2024

The goal of this pilot study is to calculate the sensitivity and specificity for discriminating tumour and benign tissues in vivo in colorectal cancer patients based on optical spectroscopy measurements. The secondary goal of this study is to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON47243

Source
ToetsingOnline

Brief title
ColoSpect study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research

Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: colon carcinoma, optical spectroscopy, rectum carcinoma, surgery

Outcome measures

Primary outcome

The sensitivity and specificity for discriminating tumour and benign tissues in

vivo in colorectal cancer patients based on optical spectroscopy measurements.

Secondary outcome

The spectral differences between in vivo and ex vivo measurements and the

difference in the biological parameters (i.e. blood content, blood oxygenation,

etc.) that are extracted from the spectral information.

Study description

Background summary

Clinical problem:
A tumour free circumferential resection margin (CRM) is an important prognostic factor for disease free and overall survival after a complete resection of colorectal cancer. A positive CRM is associated with an increased incidence of local recurrence and lower overall survival. Local recurrence is a disabling disease, with severe symptoms such as pain, faecal voiding and mechanical obstruction. In locally advanced and distal rectal tumours, a positive CRM is found in 20-30% of the procedures. Extending the resection margin reduces the risk of a positive CRM, but increases the risk of morbidity due to damage to surrounding vital structures.
Optical spectroscopy:
In recent years promising advances in cancer treatment imaging have been made with optical spectroscopy. By illuminating specific tissue with a selected light spectrum and subsequent analysis of the characteristic scattering, absorption and luminescence patterns, it is possible to obtain an *optical fingerprint* of the tissue and to discriminate between benign and malignant tissue.
Incorporation of optical spectroscopy during colorectal surgery could improve

the accuracy of the procedure. In recently performed ex vivo optical spectroscopy measurements of colorectal tissues, we observed an overall accuracy of 92% for differentiation between normal and tumour tissue. To further develop this technique for surgical applications, such as surgical margin detection, in vivo validation of tissue differentiation is necessary.

Study objective

The goal of this pilot study is to calculate the sensitivity and specificity for discriminating tumour and benign tissues in vivo in colorectal cancer patients based on optical spectroscopy measurements. The secondary goal of this study is to calculate the spectral differences between in vivo and ex vivo measurements and the difference in the biological parameters (i.e. fat content, blood oxygenation, etc.) that are extracted from the spectral information.

Study design

This study is designed as an observational study.

Study burden and risks

Participation in the study will not involve additional visits to the hospital for the included patients. Informed consent will be obtained prior to the procedure.
The total time for all measurements will take no longer than 10 minutes. Furthermore, it is highly unlikely that additional damage or discomfort will occur during the measurements. The normal surgical procedure will not be altered in any way, other than the additional time for the measurements and possible biopsy of the normal tissue. The surgeon will be blinded to the spectroscopy results.

Contacts

Public
Philips Research

High Tech Campus 34 M/S21 34 M/S21
Eindhoven 5656AE
NL
Scientific
Philips Research

High Tech Campus 34 M/S21 34 M/S21
Eindhoven 5656AE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients planned for:
1) elective colorectal surgery for either primary or recurrent colorectal cancer by an open or laparoscopic approach
2) HIPEC procedure for colorectal cancer
- Patients that have provided a signed informed consent
- Patients * 18 years old

Exclusion criteria

* Patients with suspected sensitivity to light; e.g. patients who have had photodynamic therapy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2015
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28897
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL48298.031.14
OMON	NL-OMON28897