

ColoSpect study

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28897

Bron

NTR

Aandoening

colorectal cancer

Ondersteuning

Primaire sponsor: Philips Research Eindhoven

Overige ondersteuning: Philips
Grant from KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Calculation of the sensitivity and specificity for discriminating tumor and benign tissues in vivo in colorectal cancer patients based on optical spectroscopy measurements.

Toelichting onderzoek

Achtergrond van het onderzoek

Subjects recruited at Nederlands Kanker Instituut (NKI) in Amsterdam. Single study site.

Optical spectroscopy measurements of normal and malignant colorectal tissue and healthy surrounding tissues are performed during surgery. After surgery, spectroscopic measurements are repeated on the excised tissue. To compare the spectroscopic measurements to standard histopathology assessment, biopsies will be taken from the measured locations on the excised specimen. In vivo biopsies are taken of measurement locations on healthy tissue that cannot be resected with the tumor.

Doel van het onderzoek

The primary objective of this pilot study is to calculate the sensitivity and specificity for discriminating tumor and benign tissues in vivo in colorectal cancer patients based on optical spectroscopy measurements. The secondary objective 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. blood, water and fat content and blood oxygenation) that are extracted from the spectral information.

Onderzoeksopzet

Only one measurement at day of surgery.

Onderzoeksproduct en/of interventie

Observation of surgical tissue by means of optical spectroscopy.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 03-04-2015
Aantal proefpersonen: 47
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 13-04-2015
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47243
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5175
NTR-old	NTR5315
CCMO	NL48298.031.14
OMON	NL-OMON47243

Resultaten

Samenvatting resultaten

Not applicable