Differentiation between normal tissue and malignant tissue with light spectrum analysis.

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The aim to prove that our optical spectroscopy system can provide accurate information on tissue diagnosis in these three specific tissue types. Optical spectroscopy measurement of normal tissue (including benign tumours) and malignant tissue...

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

Samenvatting

ID

NL-OMON28806

Bron
Nationaal Trial Register

Verkorte titel
OpSpect study

Aandoening

Cancer of breast, lung and liver

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute (NKI-AVL)
Overige ondersteuning: Philips Research, Minimal invasive healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Comparison of Diffuse reflectance parameters (Oxyhaemoglobin saturation, total haemoglobin content, water and fat content, collagen content, B-carotene content within the tissue as well as 3 scatter coefficients of the tissue) and Fluorescence parameters (Collagen, elastin, NADH content) within the tissue.
Comparison will be made with Pathology parameters (histology characteristics of the tissue, tumor grade, percentage necrosis) as golden standard.

Toelichting onderzoek

Achtergrond van het onderzoek

Important steps in the diagnostic work-up of malignant disease are describing the anatomical extent and histological origin of a tumor. Samples of suspected tissue are generally acquired by cytological or histological biopsy. Delay of diagnosis, and thus of subsequent initiation of therapy, is generally due to indeterminate result of cytological or histological biopsy. Successful biopsy accuracy ranges from 68% to 92%.

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 a 'chemical fingerprint' of the tissue. Because each tissue has specific variations in composition, it is possible to discriminate between tissues or more specifically discriminate between benign and malignant disease. This novel analysis technique has been proven to be more sensitive than conventional imaging techniques. Incorporation of optical spectroscopy into current diagnostic or therapeutic tools, e.g. in a biopsy needle, could improve invasive procedure localisation, thus improve procedure accuracy and outcome.

We have developed an optical spectroscopy system for measurement of tissue characteristics. In recent research of ex vivo human tissue discrimination between benign and malignant tissue was demonstrated with sensitivity and specificity of >94%.

With this study we aim to confirm the results from ex vivo research in vivo in a clinical setting.

Doel van het onderzoek

The aim to prove that our optical spectroscopy system can provide accurate information on tissue diagnosis in these three specific tissue types. Optical spectroscopy measurement of normal tissue (including benign tumours) and malignant tissue lesions will be compared to standard histopathological analysis, as golden standard.

Onderzoeksopzet

Results will be evaluated after inclusion of all 83 patients.

Onderzoeksproduct en/of interventie

Optical spectroscopy measurements of both normal tissue of breast, lung and liver and malignant lesions in these organs, in-vivo during surgical procedures. Measurements will be performed with optical needle in tissue before resection. Measurements locations will be marked for histopathology analysis and comparison.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with proven malignant lesion of breast, lung or liver or benign fibroadenoma of the breast;

2. In case of breast malignancy: Patients are scheduled for a local resection or for an ablation of the breast;

3. In case of benign fibroadenoma of the breast: Patients are scheduled for a local resection of the lesion;

4. In case of lung malignancy: Patients are scheduled for local resection, lobectomy or pneumonectomy during an open-thoracic procedure;

5. In case of liver malignancy: Patients are scheduled for local resection or hemi-hepatectomy during an open-abdominal procedure;

6. Written informed consent;

7. Patients of 18 years and older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with no proof of residual malignant disease after neo-adjuvant therapy by follow-up radiological analysis before operation;

2. 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
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2010
Aantal proefpersonen:	83
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38249
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2287
NTR-old	NTR2557
CCMO	NL32233.031.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38249

Resultaten

Samenvatting resultaten
N/A