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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28806

Source
Nationaal Trial Register

Brief title
OpSpect study

Health condition

Cancer of breast, lung and liver

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute (NKI-AVL)
Source(s) of monetary or material Support: Philips Research, Minimal invasive healthcare

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

Results will be evaluated after inclusion of all 83 patients.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	83
Type:	Actual

Ethics review

Positive opinion
Date: 06-10-2010
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38249
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A