Discrimination of benign and malignant human tissue during percutaneous interventions using optical spectroscopy techniques

Published: 21-08-2012
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON41588

Source
ToetsingOnline

Brief title
Optical detection of malignancy during percutaneous interventions

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Breast disorders
- Respiratory tract neoplasms

Synonym
Cancer, Malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: Detection, Malignancy, Optical, Spectroscopy

Outcome measures

Primary outcome

Several optical spectroscopy parameters of the targeted tissues will be analysed, specified and then compared to histopathological analysis:

1) Diffuse reflectance parameters: Oxyhaemoglobin saturation, total haemoglobin content, water and fat content within the tissue as well as 2 scatter coefficients of the tissue.

2) Fluorescence parameters: Collagen, elastin, NADH and Porhyrin content within the tissue.

3) Pathology parameters: histology characteristics of the tissue, tumor grade, percentage necrosis

The analysis of the different reflectance and fluorescence parameters will result in a specific tissue fingerprint allowing optical tissue characterization, discriminating malignant tissue from normal or benign tissue. These results will be compared to standard histopathological examination.

Primary endpoint:

To confirm that the results of the diffuse reflectance and fluorescence spectra correspond to the results from pathology. Meaning that the present study should prove that optical spectra can provide information that can be used for better localization of a biopsy needle or RFA-probe in the future.

Secondary outcome

During the measurement procedure, possible improvements of the measurement hardware will be recorded. Analysis of this documentation will provide information for possible alterations of hardware design for improved clinical applicability in the future. Special attention will be paid to observe how the procedure fits in the standard workflow of the radiologist.

Study description

Background summary

Although major advances are made in cancer imaging, daily practice in diagnostic procedures and radiological interventions are still hampered by inadequate recognition of tumor tissue at the time of the procedure. For example, recent studies have reported varying figures of overall accuracy for percutaneous lung biopsies, which respectively range between 67% and 96%. Also for liver biopsies as well as liver RFA ablation, precise positioning of the specific needle is essential for successful diagnosis or treatment. Although positioning of the biopsy needle or RFA needle can be guided by ultrasound, X-ray or CT scanning, visualization of relevant structures is often limited due to thresholds in contrast and image resolution.
Here we propose to tackle these shortcomings by using optical spectroscopy techniques (diffuse reflectance spectroscopy and fluorescence spectroscopy) that allow precise real-time monitoring of tissue characteristics at the tip of the biopsy needle or radiofrequency ablative probe. 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. In this way optical spectroscopy may be more

sensitive in tissue discrimination than conventional imaging techniques. Incorporation of optical spectroscopy technology into current diagnostic or therapeutic tools, e.g. in biopsy needles, could improve significantly the accuracy of the intended procedure and thus clinical outcome.
Earlier, we have developed an optical spectroscopy system for measurement of tissue characteristics. The concept has been tested on excised human tissue. We were able to differentiate between normal tissue (including benign tumors) and malignant tissue with a sensitivity and specificity of >95% within patient analysis. Recently, these results have been confirmed by the *OpSpect* study (NL32233.031.10), in which lung, liver and breast tissue were measured in vivo during surgery. Comparison studies in the literature have demonstrated maximum sensitivity and specificity percentages to be 83%. Our results are better compared to literature, since we are able to detect tumor using the normal tissue as internal reference for individual patients, hence removing inter-patient variation.

We conclude from our results we are able to reliably detect - in vivo - the difference between normal tissue and malignant tissue within an individual patient by means of optical spectroscopy.
The aim of the present study is to implement and test these results in a percutaneous clinical setting during standard percutaneous procedures. For this purpose a specially designed *smart* biopsy needle was developed. The radiologist will perform the core biopsy according to standard protocols. The only difference will be that during insertion of the biopsy needle optical measurements will be performed.

So, in conclusion, optical measurements will be performed in a clinical setting during standard breast/lung/liver biopsy or prior to liver RFA. The results of optical spectroscopy will be compared to histopathology results of the tissue sample.

Study objective

In our previous studies using optical spectroscopy, both ex vivo and in vivo, most promising results were obtained for tissue diagnosis. Moreover, invasive procedures for biopsy or radiofrequency ablation in these tissues are all very common. Thus, the possibility of incorporation of optical spectroscopy in needles for specific invasive procedures, such as biopsies or RFA ablations, would be of significant additional clinical value in these tissues / organs.
For this purpose a specially designed optical biopsy needle was developed, which can measure the tissue which is going to be sampled. With this observational study we aim to prove that such a needle can be used in the workflow of standard percutaneous interventions. Optical spectroscopy measurement of the lesions will be compared to standard histopathological analysis, as golden standard.

Primary Objective:

In this observational study we aim to evaluate whether optical spectroscopy can correctly diagnose malignant tissue in the existing clinical workflow of percutaneous interventions in breast, lung and liver.

Secondary Objective:
During the measurement procedure, possible improvements of the measurement hardware will be recorded. Analysis of this documentation will provide information for possible alterations of hardware design for improved clinical applicability in the future. Special attention will be paid to observe how the procedure fits in the standard workflow of the radiologist.

Further clinical development and perspectives:
This present proposed study fits within the project line *development of smart optical devices*. It is the aim that we ultimately develop a smart optical needle that can guide biopsies and radiofrequency procedures. This would allow improvement of diagnosis as well as minimal invasive treatment by RFA.
Within this trajectory three consecutive steps are foreseen:
1) Ex vivo measurements for optimizing of the technique (accomplished)
2) In vivo measurements in controlled setting for further proof of principle (accomplished: OpSpect Study, NL32233.031.10)
3) Implementation and testing in percutaneous clinical setting (present proposal).

Study design

General
The study is designed as an observational study. Patients eligible for inclusion into the study are patients who are already admitted to The Netherlands Cancer Institute (NKI-AvL) for a regular percutaneous core biopsy in breast, liver or lung or prior to a percutaneous liver RFA.
Measurements will only be performed in the interventional room prior to standard core biopsy of a suspected malignancy in breast, lung or liver or prior to planned RFA in liver metastases. Optical measurements will be performed using a specially designed CE-marked optical biopsy needle. This needle is able to perform optical measurements exact in the tissue that is going to be sampled.

Organs specific issues
Targeted lesions in breast, lung and liver will involve any lesion that is suspected to be malignant.

Procedures
It is important to note that biopsy procedures will be performed according to the standard method of performing a core biopsy, except that during insertion and just before tissue sampling, optical measurements will be performed.
The radiologist responsible for the procedure will identify the target lesion by CT or ultrasound imaging as usual. The optical biopsy needle will be

inserted like a standard biopsy needle. During this insertion real-time optical measurements will be performed. The anticipated total additional time for the whole procedure will be less than 5 minutes for breast/long/liver biopsy patients and maximal 10 minutes for patiens who will undergo percutaneous liver RFA. Sampled tissue will be analysed by the pathologist via a standardized protocol. Histopathological analysis of the tissue sample will be provided for comparison with optical analysis.

Study burden and risks

Because of the nature of this test, we do not expect any adverse events to occur that are related to technology of the optical spectroscopy hardware. Collected data will not be provided to the physicians and the planned procedure will not be influenced by the optical measurements.

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

1) Patients with a suspicious lesion in breast, lung or liver who are scheduled for a standard core biopsy procedure
2) Patient planned for percutaneous RFA of colorectal liver metastasis
3) Written informed consent
4) Patients >= 18 years old
5) Breast patients with a BIRADS score 4 or 5

Exclusion criteria

1) Patients who have high risk of bleeding
2) Patients with suspected sensitivity to light; e.g. patients who have had photodynamic therapy
3) Patients who have a history of breast cancer and/or who have received prior chemotherapy, endocrine therapy, or radiation therapy
4) Patients who have breast implants
5) Patients needing a stereotactic breast biopsy (i.e. non palpable-, ultrasound opaque lesions)

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):	08-10-2012
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-04-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	04-11-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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: 21152
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40578.031.12
OMON	NL-OMON21152