In vivo identification of peripheral nerve bundles during surgery using optical spectroscopy techniques: a pilot study

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With this pilot study we aim to prove that our optical spectroscopy system can provide accurate identification of nerve tissue during surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON37194

Source
ToetsingOnline

Brief title
NerveSpect

Condition

- Skin neoplasms malignant and unspecified
- Skin and subcutaneous tissue therapeutic procedures

Synonym
haed and neck malignancies, melanoma, rectal cancer, soft tissue tumours

Research involving
Human

Sponsors and support

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

Intervention

Keyword: optical spectroscopy, peripheral nerves

Outcome measures

Primary outcome

Several optical spectroscopy parameters of the targeted tissue will be analysed and specified.

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

Fluorescence parameters: Collagen, elastin, NADH content within the tissue.

The analysis of the different reflectance and fluorescence parameters will result in a specific tissue fingerprint allowing optical tissue specific characterization of nerve tissue of the hypogastric plexus.

Primary Objective:

In this pilot study we aim to evaluate whether optical spectroscopy is able to differentiate between nerve tissue and surrounding tissue.

Secondary outcome

Secondary Objective:

During the measurement procedure, possible improvements of the measurement

hardware will be recorded and the handling during surgery will be evaluated.

Study description

Background summary

Clinical problem:
Damage to nerve bundles caused by surgery can lead to temporary or long time morbidity. In some cases, damage is inevitable because tumour invasion or encasement requires sacrifice of the nerve. However, in many surgical procedures nerve bundles can and should be spared. The identification of these bundles can be challenging, especially in patients who underwent previous surgery in the same area or in those who received radiotherapy prior to surgery. The consequences of nerve damage have a significant impact on the patients* quality of life.

Clinical examples:
In rectal surgery, damage of the hypogastric plexus results in bladder dysfunction (e.g. urine retention, stress or urge incontinence, loss of bladder sensitivity) and sexual disorders (e.g. erection and ejaculation disorders, decreased vaginal lubrication). Bladder dysfunction occurs in 20-30%, and sexual disorders in approximately 30% of patients after rectal surgery1;2.
Facial nerve paralysis is a devastating complication of oncologic procedures in the head and neck such as in parotidectomy. Post-operative facial nerve dysfunction involving some or all of the branches of the nerve is the most frequent early complication of parotid gland surgery. Temporary facial nerve paresis, involving all or just one or two branches of the facial nerve, and permanent total paralysis have occurred, respectively, in 9.3% to 64.6% and in 0% to 8% of parotidectomies, reported in the literature3;4.

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 tissue5;6. In this way optical spectroscopy may be more sensitive in tissue discrimination than conventional imaging techniques7.
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. Recently, we have developed an optical spectroscopy system for in vivo measurement of tissue characteristics. The concept has first been tested on excised human tissue. In this ex-vivo study we evaluated the *optical fingerprint* of normal tissue and

malignant tissue of breast, lung and liver. We were able to differentiate between normal tissue (including benign tumours) and malignant tissue with a sensitivity and specificity of >94% within patient analysis. Comparison studies in the literature have demonstrated maximum sensitivity and specificity percentages to be 83%.

Spectroscopy of nerve tissue:
Several groups have studied the application of optical spectroscopy to identify nerve tissue. Rathmell and Brynolf have investigated the use of optical spectroscopy to identify the epidural space and the brachial plexus in an in vivo model in swine8;9. They were able to reliably identify nerve tissue in vivo using spectroscopic contrast for the optical absorption of lipids and hemoglobin. In these studies, nerve tissue was distinguished from surrounding tissue by means of their lipid and hemoglobin content. The transition of the needle tip from skeletal muscle to the nerve target region was associated with higher lipid parameter values and lower hemoglobin parameter values.
There is little known about the fluorescence of nerve tissue. Adhikary et al. focused on bovine and mice models to detect bovine central nervous system (CNS) tissue in meat products10. They show that spectral signatures of lipofuscin enables the detection of CNS-tissue in meat products.

Study objective

With this pilot study we aim to prove that our optical spectroscopy system can provide accurate identification of nerve tissue during surgery.

Study design

The study is designed as a pilot study.

Patients eligible for inclusion into this study are patients admitted to The Netherlands Cancer Institute (NKI-AvL) for elective surgery.

Suitable patients:
- inguinal or axillary lymph node dissection (femoral nerve and side braches, thoracodorsal nerve)
- cervical lymph node dissection (great auricular nerve)
- parotidectomy (facial nerve)
- patients undergoing rectal resection for rectal carcinoma

Procedures
The surgeon responsible for the operation will identify the nerve bundle. The blunt tip optical needle will be placed on the nerve bundle as well as on surrounding tissue and measurements will be performed.

Study burden and risks

During the operation, during up to 10 minutes optical spectroscopic measurements are performed.
There are no anticipated risks for patients by participating in this study.
Extensive research by and with the optical spectroscopy methods on human tissue have shown no adverse events.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Patients planned for elective inguinal or cervical lymph node dissection, parotidectomy, rectal resection or resection of soft tissue tumour.
•Written 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:	Recruiting
Start date (anticipated):	20-12-2012
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Not approved

Date:	26-09-2013
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: 28049
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL40893.031.12
OMON	NL-OMON28049