Optical detection of peripheral nerve bundles during surgery.

No registrations found.

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

Summary

ID

NL-OMON28049

Source
Nationaal Trial Register

Health condition

The study is designed as an observational pilot study. The measured diffuse reflectance and fluorescence spectra acquired in this pilot study will not be shared with the physicians during the interventional procedure.

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

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

Sponsors and support

Primary sponsor: Philips Research Eindhoven
HTC34
5656 AE Eindhoven
Source(s) of monetary or material Support: Philips Research Eindhoven
HTC34

5656 AE Eindhoven

Intervention

Outcome measures

Primary outcome

The ability of optical spectroscopy to differentiate between nerve tissue and surrounding tissue.

Secondary outcome

Possible improvements of the measurement hardware and evaluation of the handling during surgery.

Study description

Background summary

N/A

Study objective

Primary Objective:

The goal of this pilot study is to evaluate whether optical spectroscopy is able to differentiate between nerve tissue and surrounding tissue.

Secondary Objective:

During the measurement procedure, possible improvements of the measurement hardware will be recorded and the handling during surgery will be evaluated.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients planned for elective inguinal, axillary or cervical lymph node dissection or parotidectomy , patients with rectal cancer undergoing rectal surgery and patients undergoing resection of a soft tissue tumour;

2. Patients that have provided a signed informed consent;

3. 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 non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-12-2012
Enrollment:	22
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-12-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37194
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3577
NTR-old	NTR3735
CCMO	NL40893.031.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON37194

Study results

Summary results
N/A