Raman Spectroscopy in Head and Neck Oncology

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Accurately identify the molecular/ biochemical 'fingerprints' of the tissue structures and cell types within normal and malignant mucosa from the oral cavity, in particular the edge of the tongue and the floor of the mouth, based on Raman...

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

Summary

ID

NL-OMON38366

Source
ToetsingOnline

Brief title
Raman Spectroscopy in Head and Neck Oncology

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and Neck Squamous Cell Carcinoma (HNSCC), tumor

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: HNSCC, Oncology, Raman, Spectroscopy

Outcome measures

Primary outcome

The primary outcomes are the characteristic Raman spectra of the tissue structures and cell types within normal and malignant mucosa from the oral cavity (in particular the edge of the tongue and the floor of the mouth), as a reflection of the molecular/ biochemical composition of these tissues.

Secondary outcome

• Determine what the difference is in the molecular/ biochemical *fingerprints* between the normal-looking mucosa adjacent to the tumor and the normal mucosa of the contralateral side of the oral cavity.

• Determine what the difference is in the molecular/ biochemical *fingerprints* between normal and malignant mucosa of the oral cavity.

• Determine what the difference is in the molecular/ biochemical *fingerprints* between different patients (interpatient variance).

• Determine what the sensitivity and specificity of Raman spectroscopy is, compared to the gold standard (histological assessment).

• Build a multivariate diagnostic model that can distinguish between normal and malignant mucosa from the oral cavity

Study description

Background summary

Head and Neck Squamous Cell Carcinomas (HNSCC) are associated with severe disease and high mortality, which is due mainly to the development of metastases and recurrences over time. It is known that there is a higher chance to develop metastases and recurrences when the surgical tumor resection is incomplete. The current gold standard to ensure tumor-free margins during surgery, histological assessment, is time-consuming and is dependent on the experience of the surgeon and on subjective assessment of the surgeon and the pathologist. A new technique is therefore needed that can provide objective real-time information about the composition of tissues during surgical tumor resections in the head and neck region.

During tumorigenesis the morphologically visible malignant transformation of an epithelial cell is preceded by changes in its biochemical composition. Raman spectroscopy is an optical technique based on inelastic scattering of light by molecules. The concentration of a specific molecule in a tissue defines its contribution to the Raman spectrum. Since a Raman spectrum of a single molecule is very specific for that molecule, a Raman spectrum of a tissue can be seen as a molecular or biochemical *fingerprint* of that tissue. Because different types of tissue will vary in their overall molecular composition, their Raman spectra will also differ. Raman spectroscopy can consequently provide detailed information on the biochemical composition of specific tissue structures and cell types.

Raman spectroscopy is a non-destructive and non-invasive technique that needs no tissue preparation. Moreover, with this technique it is possible to obtain real-time clinical information about the investigated tissues. Based on these characteristics Raman spectroscopy is a powerful candidate for in vivo and ex vivo real-time guidance of oncological surgical resections in head and neck region.

Study objective

Accurately identify the molecular/ biochemical 'fingerprints' of the tissue structures and cell types within normal and malignant mucosa from the oral cavity, in particular the edge of the tongue and the floor of the mouth, based on Raman spectroscopy, in order to make a first step towards in vivo applications of this technique.

Study design

- prospective collection of tissue samples
- observational research (Raman mapping experiments)

Study burden and risks

To close the biopsy defects during surgery, none or one soluble suture will be

used. This suture can give some discomfort or pain while eating or speaking, however it is expected that this will not significantly contribute to the discomfort related to the clinically indicated resection of the malignant lesion. Patients are postoperative treated according to a protocol which will lead to accurate pain management and antiseptic care. Because of this and because the biopsies will be very small (6 mm cross-cut), the chance of infection and bleeding is very small.

For future purposes a blood sample will be collected additional to pre- or post-operation blood control, in order to correlate the results of Raman spectroscopy with molecular diagnostic methods.

There are no risks associated for the patient when the biopsies of the resection material are collected.

No additional treatments, consults or tests are necessary for the patient.

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

• Surgical oncologic procedure because of an untreated SCC of the oral cavity
• Signed informed consent
• Male and female
• Age > 18 years old
• No distant metastasis

Exclusion criteria

• Another type of tumor in the head and neck region (non SCC)
• Pre-operative treatment (chemotherapy or radiotherapy)
• Presence of distant metastases (M1)
• Patients with HIV, CMV or Hepatitis C

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL37340.078.11