# Lymph node metastasis detection using light reflectance spectroscopy

Published: 12-02-2018
Last updated: 12-04-2024

To accurately differentiate between metastatic and non-metastatic lymph nodes using light reflectance spectroscopy.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON44169

**Source**
ToetsingOnline

**Brief title**
LIGHT

### Condition

- Other condition

**Synonym**
Cancer spread to lymph node

**Health condition**

Hoofd-halskanker en lymfekliermetastase

**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:** Lymf node metastasis, Reflectance spectroscopy

## Outcome measures

### Primary outcome

The optical absorption properties of the metastatic and non-metastatic LN.

### Secondary outcome

N/A

# Study description

### Background summary

Head and neck squamous cell carcinoma (HNSCC) has a high propensity to metastasize to cervical lymph nodes (LN). This is associated with a markedly reduced survival. The management of patients with a clinically negative neck (cN0) is still a controversial issue. One policy is to surgically treat all patients with a neck dissection (ND). This prevents occult metastases becoming advanced but also implies over treating many patients. Another option is to actively monitor the cN0 neck. The existing techniques to do this, however, all have limitations in detecting small metastatic deposits. A possible solution for the management of cN0 necks is to perform a sentinel node biopsy. If the sentinel node contains malignant cells, a ND is recommend. Currently this ND is done in a second (staged) procedure as histopathologic examination of the sentinel node takes time. Single fiber reflectance spectroscopy (SFR) has the potential to significantly reduce the number of second stage surgery by in-vivo, immediate detection of metastases in the sentinel node. LN with metastases undergo physiological changes that can be detected by SFR. A previous similar study showed very promising results in mediastinal LN in patients with lung cancer. In this study we would like the first step towards using SFR to detect metastases in sentinel LN in patients with HNSCC. We will do this by investigating if SFR can accurately discriminate metastatic cervical LN from non-metastatic LN.

### Study objective

To accurately differentiate between metastatic and non-metastatic lymph nodes using light reflectance spectroscopy.

### Study design

Observational non-randomized cohort study.

### Study burden and risks

The spectroscopy measurements will be performed while patients are under general anesthesia. Measurements will be performed in vivo on tissues that will be excised regardless of this study. The patients will not benefit from the study.

## 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

- Diagnosis of a primary head and neck squamous cell carcinoma, all subsites, all TNM-stages
- A indication for a neck dissection

### Exclusion criteria

- Prior treatment of the tumor ((chemo)radiation or surgery)
- Age < 18
- No understanding of Dutch language
- Serious other illness

## Study design

### Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2018 |
| Enrollment: | 16 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 12-02-2018 |
| Application type: | First submission |
| 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 | NL61999.078.17 |