

# Lymphoscintigraphy of the pretreated neck in head and neck squamous cell carcinoma

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To analyze the value of lymphatic mapping in HNSCC patients with a previously treated neck.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30277

### Source

ToetsingOnline

### Brief title

PRET study

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

### Synonym

head and neck cancer, head and neck squamous cell carcinoma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** head and neck cancer, lymphoscintigraphy, recurrent, second primary tumor

## Outcome measures

### Primary outcome

Primary endpoint is the lymph node drainage of recurrent or second primary HNSCC in the previously treated neck.

### Secondary outcome

Secondary endpoints are alteration of lymphatic drainage after previous treatment of the neck and influence of lymph node mapping (and sentinel node biopsy or cytology) on treatment planning.

## Study description

### Background summary

Treatment of lymph nodes is based on the knowledge that the pattern of metastatic spread is predictable, and related to site, size and histopathological status of the primary tumor. However, any disturbance of normal drainage by operation, radiotherapy or recurrent disease, can result in other pathways of lymphatic drainage with dissemination of cancer cells. Lymphoscintigraphy is able to supply a complete map of the lymphatic drainage and thereby tailoring treatment which may minimise the extent of under- and overtreatment. If accessible the status of these sentinel lymph nodes can be determined by histopathological examination of excised sentinel nodes (sentinel node biopsy procedure) or (ultrasound guided) fine needle aspiration cytology of these nodes.

### Study objective

To analyze the value of lymphatic mapping in HNSCC patients with a previously treated neck.

### Study design

This is an observational non-randomized single-institute pilot study.

of radiolabeled-colloid prior or during anesthesia for endoscopy, lymphoscintigraphy using a gamma camera and if possible (depending on the localization) surgical excision of the sentinel lymph node(s) or (ultrasound guided) fine needle aspiration cytology.

### **Study burden and risks**

Lymphoscintigraphy and sentinel node biopsy and aspiration are procedures which are used routinely in several tumor types. In the literature on head and neck cancer no serious adverse events have been reported using these techniques. Sentinel node biopsy and ultrasound guided fine needle aspiration cytology will be performed by experienced head and neck surgeons, radiologist and pathologist.

## **Contacts**

### **Public**

Vrije Universiteit Medisch Centrum

De Boelelaan 1117

1081 HV

Nederland

### **Scientific**

Vrije Universiteit Medisch Centrum

De Boelelaan 1117

1081 HV

Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

recurrent or second primary head and neck cancer  
suitable for peritumoral injection  
previous treatment of lymph nodes  
clinically N0 neck

## Exclusion criteria

age <18 or > 80years

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2006

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL14237.029.06