

# Ultrasound guided fine needle aspiration cytology and sentinel node biopsy in the detection of occult lymph node metastases of early oral and oropharyngeal cancer

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Evaluation and comparison of sentinel node biopsy (SNB) and ultrasound guided fine needle aspiration cytology (USgFNAC) in the management of the clinically negative neck in patients planned for transoral excision of oral and oropharyngeal squamous...

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

## Summary

### ID

NL-OMON31627

### Source

ToetsingOnline

### Brief title

SNUS trial

### Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

### Synonym

oral cancer, oral squamous cell carcinoma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw DoelmatigheidsOnderzoek VEMI

## Intervention

**Keyword:** head and neck cancer, lymph node metastases, sentinel node, ultrasound guided fine needle aspiration cytology

## Outcome measures

### Primary outcome

Diagnostic accuracy of selection for treatment of the neck by strategies based on USgFNAC and/or SNB.

### Secondary outcome

Number of neck dissections, quality of life, patients\* perspective and cost-effectiveness of selection strategies based on USgFNAC and/or SNB or elective treatment of the neck.

## Study description

### Background summary

The treatment of the clinically negative neck (N0) in small oral or oropharyngeal carcinoma is controversial. When there is a low likelihood of occult (clinically undetectable) lymph node metastases, is the choice between elective neck dissection or a wait and see policy. Because of the risk of over- and undertreatment there is need for a reliable diagnostic technique. Ultrasound guided fine needle aspiration cytology (USgFNAC) is routinely used in the detection of lymph node metastases. The sentinel node procedure is a promising technique which is nowadays routinely used in other tumor types.

### Study objective

Evaluation and comparison of sentinel node biopsy (SNB) and ultrasound guided fine needle aspiration cytology (USgFNAC) in the management of the clinically negative neck in patients planned for transoral excision of oral and

oropharyngeal squamous cell carcinoma.

## Study design

Prospective, observational study of 60 patients to define accuracy of either technique in a head-to-head comparison, and to model the cost effectiveness of USgFNAC and/or SNB-based diagnosis-therapy combinations.

The volume and direct medical costs of treatment and follow-up will be extracted from hospital databases and patient files. A model will evaluate the costs and effects of possible diagnostic and treatment strategies in this patient group.

## Study burden and risks

Sentinel node procedure and ultrasound guided fine needle aspiration cytology are used routinely in several tumor types. In the literature on head and neck cancer no serious adverse events have been reported using these diagnostic techniques. The diagnostic techniques will be performed by experienced head and neck surgeons, nuclear physicians, radiologists and pathologists.

## 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

Patients with a primary biopsy proven oral/oropharyngeal squamous cell carcinoma which can be locally (transorally) resected and a clinically negative neck.

### Exclusion criteria

Transoral excision not possible

Neck entered for reconstruction

Clinical lymph node metastasis

## 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): 01-01-2008

Enrollment: 60

Type: Anticipated

## Ethics review

Approved WMO  
Date: 07-11-2007  
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	NL19558.029.07