

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

No registrations found.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Positive opinion    |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | -                   |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON26273

### Source

NTR

### Brief title

SNUS (Sentinel Node versus UltraSound)

### Health condition

1. Head and neck cancer;
2. Lymph node metastases;
3. Sentinel node biopsy;
4. Ultrasound guided fine needle aspiration cytology;
5. Neck dissection;
6. Costs;
7. Quality of life.

## Sponsors and support

**Primary sponsor:** VU University Medical Centre, department of Otolaryngology / Head and Neck Surgery

**Source(s) of monetary or material Support:** Zon-Mw

## Intervention

## Outcome measures

### Primary outcome

Diagnostic accuracy of selection for treatment of the neck by strategies based on ultrasound guided fine needle aspiration cytology and/or sentinel node biopsy.

### Secondary outcome

number of neck dissections, quality of life, patient's perspective, cost-effectiveness of selection strategies based on ultrasound fine needle aspiration cytology and/or sentinel node biopsy or elective treatment of the neck.

## Study description

### Background summary

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

### Study objective

Application of sentinel node biopsy (in comparison to or combined with ultrasound guided fine needle aspiration cytology) improves the detection of occult lymph node metastases to a clinically relevant extent.

### Intervention

Each patient will undergo ultrasound guided fine needle aspiration cytology (standard procedure) and sentinel node biopsy procedure.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1. Patients with a primary biopsy proven oral/oropharyngeal squamous cell carcinoma;
2. Planned for transoral excision;
3. Without clinically suspected cervical lymph nodes.

### Exclusion criteria

1. Transoral excision not possible;
2. Neck entered for reconstruction;
3. Clinical lymph node metastasis;
4. Age < 18 or > 80 year.

## Study design

## Design

|                     |                         |
|---------------------|-------------------------|
| Study type:         | Interventional          |
| Intervention model: | Other                   |
| Masking:            | Open (masking not used) |
| Control:            | N/A , unknown           |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-01-2008          |
| Enrollment:               | 60                  |
| Type:                     | Actual              |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 24-09-2007       |
| Application type: | First submission |

## 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      |
|----------|---------|
| NTR-new  | NL1025  |
| NTR-old  | NTR1057 |

**Register**

Other  
ISRCTN

**ID**

VUmc : 2007/190 (projectnumber VUmc)  
ISRCTN wordt niet meer aangevraagd

## Study results

**Summary results**

not applicable