

Sentinel Node Biopsy in the Management of Oral and Oropharyngeal Squamous Cell Carcinoma

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Evaluation and comparison of SNB and USgFNAC in the management of clinical negative neck in patients planned for transoral excision of oral and oropharyngeal squamous cell carcinoma.

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON29965

Source

ToetsingOnline

Brief title

SENT trial

Condition

- Metastases

Synonym

oral cancer, oral cavity carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: eigen afdeling

Intervention

Keyword: lymph node metastases, oral cancer, sentinel node, ultrasound

Outcome measures

Primary outcome

Primary endpoint is neck recurrence-free rate 3 years after registration in the cohort of patients who are SNB negative at registration.

Secondary outcome

Secondary endpoints also include diagnostic value of SNB compared with USgFNAC.

Study description

Background summary

The management of the clinically negative (N0) neck in small oral and oropharyngeal cancer is controversial issue. When there is merely a high likelihood of occult lymph node metastases, the choice is between elective treatment and watchful waiting. Because of the risk for under- and overtreatment a sensitive and specific diagnostic technique is warranted. At the VUmc US-guided fine needle aspiration cytology (USgFNAC) is routinely used for the detection of occult lymph node metastases. The technique of sentinel node biopsy (SNB) is a promising diagnostic technique which is nowadays routinely used in other tumor types.

Study objective

Evaluation and comparison of SNB and USgFNAC in the management of clinical negative neck in patients planned for transoral excision of oral and oropharyngeal squamous cell carcinoma.

Study design

This is an observational non-randomized multicenter trial approved by EORTC. No randomization is performed, because a randomized trial would have to test a non-inferiority hypothesis and would require over 1000 patients. In the VU medical center USgFNAC is added for comparison.

Intervention

Sentinel node biopsy procedure which includes injection of radiolabeled-colloid, lymphoscintigraphy using a gamma camera and surgical excision of the sentinel lymph node(s) during anesthesia for panendoscopy

Study burden and risks

In current clinical practice these patients undergo USgFNAC and/or further imaging like CT, MRI or PET. Lymphoscintigraphy and sentinel node biopsy are procedures which are used routinely in other tumor types. In the literature on head and neck cancer no serious adverse events have been reported using these techniques. Through a more extensive diagnostic work-up for staging the neck the chance of missing occult lymph node metastases is decreased.

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

oral / oropharyngeal squamous cell carcinoma
suitable for transoral excision
clinically negative neck (no lymph node metastases)

Exclusion criteria

previous treatment of the neck

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2006

Enrollment: 40

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	NL13122.029.06