

# Sentinel node biopsy in the detection of cervical occult lymph node metastases in patients with parotid gland carcinoma.

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To evaluate the feasibility and prove the concept of sentinel node biopsy in patients with carcinoma of the parotid gland and scheduled for parotidectomy and elective neck dissection.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Metastases
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32680

### Source

ToetsingOnline

### Brief title

SNparotis-study

### Condition

- Metastases

### Synonym

parotid carcinoma; salivary gland tumor

### 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:** lymph node metastases, parotid carcinoma, sentinel node

## Outcome measures

### Primary outcome

Primary endpoint is the feasibility and validation of the sentinel node biopsy procedure in patients with carcinoma of the parotid gland with N0 neck scheduled for parotidectomy with elective neck dissection.

### Secondary outcome

NA

## Study description

### Background summary

In patients with carcinoma of the parotid gland the management of the clinically negative neck is a controversial issue. In most patients a selective (L I-III) neck dissection is performed but a substantial number of them are futile. The current diagnostic techniques are not accurate enough to detect occult lymph node metastases. The sentinel node procedure may be useful to select patients for neck dissection and reduce the number of futile neck dissections.

### Study objective

To evaluate the feasibility and prove the concept of sentinel node biopsy in patients with carcinoma of the parotid gland and scheduled for parotidectomy and elective neck dissection.

### Study design

This is an observational non-randomized validation study. Patients will undergo peritumoral injection of radiolabelled-colloid, lymphoscintigraphy, surgical excision of the sentinel lymph node(s) in the neck and detailed histopathological examination.

## Study burden and risks

Sentinel node biopsy is a procedure which is used routinely in other tumor types. In the literature on head and neck cancer no serious adverse events have been reported using these techniques. Sentinel node biopsy will be performed by experienced head and neck surgeons during surgery of the primary tumor. Neck dissection in combination with sentinel node biopsy stages the neck more accurately (by detecting micrometastases and single tumor cells which may be missed during routine examination of lymph nodes) than neck dissection alone. Findings from this validation study may have implications for future treatment planning.

## 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 carcinoma of the parotid gland

No lymph node metastases on CT, MRI or USgFNAC

Scheduled for parotidectomy and elective (selective or modified radical) neck dissection

## Exclusion criteria

Clinical lymph node metastases

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Date: 21-10-2008

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	NL24715.029.08

## Study results

### Summary results

Trial never started