

Detection of occult lymph node metastasis of laryngeal carcinoma by sentinel node biopsy

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To evaluate the feasibility and potential of sentinel node biopsy in patients with (recurrences of) laryngeal carcinomas and clinically negative neck undergoing total laryngectomy and neck dissection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32214

Source

ToetsingOnline

Brief title

LARS-study

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym

laryngeal cancer; larynxcarcinoma

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: laryngeal cancer, lymph node metastases, sentinel node biopsy

Outcome measures

Primary outcome

Primary endpoint the feasibility and validation of sentinel node biopsy procedure in patients with (recurrences of) laryngeal carcinomas scheduled for total laryngectomy.

Secondary outcome

NA

Study description

Background summary

In patients with laryngeal carcinoma and a clinically negative neck treated by laryngectomy a substantial number of futile neck dissections is performed in clinical practice. Intraoperative identification and histopathological examination of the sentinel node may be used to select patients for neck dissection and reduce the number of futile neck dissections.

Study objective

To evaluate the feasibility and potential of sentinel node biopsy in patients with (recurrences of) laryngeal carcinomas and clinically negative neck undergoing total laryngectomy and neck dissection.

Study design

This is an observational non-randomized pilot study. During general anesthesia for laryngectomy and neck dissection peritumoral injections of radiolabeled-colloid, intraoperative identification of the sentinel node(s) using a hand held gamma probe and surgical excision of the sentinel lymph node(s) 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 exploration of the neck for laryngectomy and neck dissection.

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 scheduled for laryngectomy and (selective) neck dissection for (advanced or recurrent) laryngeal carcinoma

Primary tumor accessible for peritumoral injection of radiolabeled colloid on direct laryngoscopy

No lymph node metastases on CT, MRI or ultrasound guided fine needle aspiration cytology

Exclusion criteria

Clinical lymph node metastases
Tumor not accessible for endoscopic injection
age > 80 jaar

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 23-06-2008

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 20-06-2008

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	NL22938.029.08