Prospective registration study on the sentinel node procedure for bulky squamous cell carcinoma of the nasal vestibule

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To prospectively document the introduction of the sentinel node procedure for bulky cT1-T2N0 nasal vestibule carcinoma in patients at risk of nodal involvement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49091

Source
ToetsingOnline

Brief title
Sentinel NOSE study

Condition

- Other condition
- Skin neoplasms malignant and unspecified

Synonym
anterior nose cancer, nasal vestibule carcinoma

Health condition

hoofd hals maligniteiten

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: RIHS PI budget

Intervention

Keyword: head and neck cancer, nasal vestibule, sentinel node, squamous cell carcinoma

Outcome measures

Primary outcome

The primary endpoint of this study will be successful identification of

sentinel nodes on lymphoscintigraphy and SPECT imaging. The procedure will be

considered feasible when one or more sentinel nodes can be identified and

localized in at least 7 out of the 10 patients.

Secondary outcome

The secondary outcomes will be: yield of at least one lymph node after biopsy,

incidence of surgical complications and pain score during and after peritumoral

tracer injection and tracer.

Study description

Background summary

Management of the neck in Wang cT1-T2N0 nasal vestibule carcinoma (NVC) has been an ongoing point of discussion. Due to the rarity of this disease, regional recurrence rates vary widely between 0% up to 23%. In general, literature recommends adequate neck staging followed by a watchful waiting policy, as average regional recurrence rates are low (5-10%).
However, according to recent findings, a subset of patients with large or voluminous cT1-T2N0 NVC is deemed at high risk of nodal involvement (20-40% regional recurrence) but receive no elective treatment, although it is well known that presence of nodal metastases impacts the prognosis of head and neck

cancer (HNC) dramatically. Whereas elective neck dissection may be too aggressive, sentinel node biopsy (SNB) has been proven a reliable and safe alternative to bridge the gap between imaging and neck dissection.
SNB is currently routinely employed in most HNC centres in the Netherlands and is considered state of the art care, but its application in HNC is limited to oral cavity carcinoma and squamous cell carcinoma of the skin. Following the observation of increased risk of (occult) nodal metastases and regional recurrence in bulky tumors, the sentinel node procedure seems ideally suited for cT1-T2N0 NVC patients. Its superficial tumor localization is easily accessible for peritumoral Tc-99m-nanocolloid-ICG tracer injection. The purpose of this prospective registration study is to document the clinical introduction of the sentinel node procedure for bulky nasal vestibule carcinoma in our centre by protocol, and to identify and address possible unexpected difficulties specific for this tumor site. Ultimately, the goal will be routine and wide implementation of SNB in the NVC subgroup known to be at risk of nodal involvement, as a means to improve regional disease staging and control.

Study objective

To prospectively document the introduction of the sentinel node procedure for bulky cT1-T2N0 nasal vestibule carcinoma in patients at risk of nodal involvement.

Study design

Prospective registration study.

Study burden and risks

The sentinel node procedure is considered state of the art care, but implies additional invasive procedures for the patient. Therefore, proper introduction by protocol and proper documentation are necessary. Prior to radiotherapy, 4 subcutaneous peritumoral injection with radioactive Tc-99m-nanocolloid-ICG will be given at the Nuclear Medicine department, followed by SPECT imaging. Pain may be experienced during tracer injection, which will be scored as one of the study outcomes to assess tolerability. After tracer injection, patients will undergo sentinel lymph node biopsy. They will be at low risk of minor surgical complications such as postoperative hematoma or infection. This is offset by possible earlier detection of otherwise occult nodal metastases and a corresponding higher chance of curation by adequate neck treatment. The sentinel node procedure will become the recommended neck staging tool, however, patients will have the option to opt-out of the procedure and hence this study.

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

* WHO performance score of 0, 1 or 2.
* Newly diagnosed T1 or T2 squamous cell carcinoma of the nasal vestibule.
* Tumor diameter *1.5 cm and/or tumor volume *1.5cm3
* Clinically negative neck (N0).
* Patients planned to undergo curative treatment.

Exclusion criteria

* Prior allergic reaction to either indocyanide green, 99m-Technetium nanocolloid or human colloidal albumin.
* Pregnancy.

* Previous surgery or radiotherapy of the neck.
* Concurrent secondary head-and-neck tumor.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70706.091.20

Study results

Date completed:	20-11-2023
Actual enrolment:	10