Assessment of contralateral cervical metastases using sentinel lymph node biopsy in patients with lateralized oral carcinoma: A pilot study

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This study aims to explore the rate of contralateral lymphatic drainage and occult contralateral metastases in patients with lateralized OSCC, a clinically negative contralateral neck and clinical ipsilateral lymph node metastases metastases or a…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON55337

Source
ToetsingOnline

Brief title
CONSENT

Condition

- Head and neck therapeutic procedures

Synonym
lymph node metastasis, Mouth cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contralateral cervical metastases, Oral cavity carcinoma, Sentinel lymph node biopsy

Outcome measures

Primary outcome

The rate of contralateral lymphatic drainage and occult CLNM in patients with

lateralized OSCC, a clinically negative contralateral neck and a clinically

ipsilateral positive neck metastases or a clinically negative ipsilateral neck

in advanced stage OSCC.

Secondary outcome

Not applicable

Study description

Background summary

In oral squamous cell carcinoma (OSCC), contralateral lymph node metastases (CLNM) strongly correlates with poor prognosis. Numerous studies have shown survival benefit of elective neck dissection (END), as compared to therapeutic neck dissection in clinically node-negative (cN0) OSCC patients. However, in regard of the clinically negative contralateral neck in OSCC patients, there is an ongoing discussion concerning the benefit of elective treatment. This debate is sustained by the varying incidence of CLNM in OSCC among institutions (0.9%-36%). Because of confusing guidelines and the relatively low incidence of CLNM, many patients will receive unnecessary treatment of the contralateral clinically negative neck. Whereas neck dissection and irradiation of the neck are associated with significant morbidity. Sentinel lymph node biopsy (SLNB) might offer a solution to the dilemma that arises in the clinically negative contralateral neck in patients with lateralized OSCC and ipsilateral lymph node metastases. Since SLNB would enable to accurately select those that are eligible for treatment of the contralateral neck. Thus, avoiding overtreatment of the contralateral neck, since only those with positive contralateral sentinel lymph nodes (SLN) will be eligible for additional treatment of the

contralateral neck.

Study objective

This study aims to explore the rate of contralateral lymphatic drainage and occult contralateral metastases in patients with lateralized OSCC, a clinically negative contralateral neck and clinical ipsilateral lymph node metastases metastases or a clinically negative ipsilateral neck in advanced stage OSCC, with SLNB. Secondly, we aim to investigate whether a full-sized study (n=180) regarding the incidence of (occult) contralateral metastases in patients lateralized OSCC, a clinically negative contralateral neck and clinical ipsilateral lymph node metastases or a clinically negative ipsilateral neck in advanced stage OSCC, by means of SLNB, is eligible.

Study design

The proposed study is designed as a prospective single-center pilot study and will be conducted in the UMC Utrecht.

Intervention

All patients will undergo additional lymphoscintigraphy. In those with contralateral lymphatic drainage, additional SLNB of the contralateral neck will be performed simultaneous to standard surgery (i.e. tumor resection and ipsilateral neck dissection).

Study burden and risks

Extra burden for patients concerns additional lymphoscintigraphy and any additional dissection of SLN(s) in the contralateral neck. Complications after SLNB are uncommon and there is substantial experience in the UMC Utrecht regarding lymphoscintigraphy and SLNB. Besides, patients may also benefit from the study, as occult contralateral cervical metastases can be detected and treated at an early stage, which implies better oncological outcome. Therefore, the risks of participation in this study are considered acceptable for the subjects.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. The patient has provided written informed consent authorization before participating in the study.
2. The patient has a diagnosis of primary lateralized oral squamous cell carcinoma, that does not involve the midline and is anatomically located in: mucosal lip, buccal mucosa, lower alveolar ridge, upper alveolar ridge, retromolar gingiva (retromolar trigone), floor-of-the-mouth, hard palate or oral (mobile) tongue.
3. Clinical nodal staging of the positive ipsilateral neck (N1-N3) or a negative ipsilaterale neck (N0) in case of T3-T4 primary lateralized oral squamous cell carcinoma, has been confirmed by ultrasound, MRI and/or fine needle aspiration cytology within 30 days of the SLN procedure.
4. Clinical nodal staging of the negative contralateral neck (N0) has been confirmed by neg-ative results from ultrasound, MRI and/or fine needle aspiration cytology within 30 days of the SLN procedure.
5. The patient is a candidate for surgical tumor resection and ipsilateral neck dissection.
6. Patients with prior malignancy in the head and neck area are allowed, provided the patient meets both of the following criteria:

• Underwent potentially curative therapy for all prior head and neck malignancies and is deemed low risk for recurrence; and
• No head and neck malignancy for the past five years (except effectively treated basal cell or squamous cell skin cancer) and no evidence of recurrence.
7. The patient is >=18 years of age at the time of consent.
8. The patient has an ECOG status of Grade 0-2.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. The patient has a diagnosis of squamous cell carcinoma of the head and neck in the fol-lowing anatomical areas: non-mobile base of the tongue, oropharynx, nasopharynx, hy-popharynx, and larynx.
2. The patient is incapacitated.
3. The patient has had a previous allergic reaction after administration of a radionuclide tracer.
4. The patient has had other nuclear imaging studies, conducted within 2 days (48 hours) of injection.
5. The patient has a history of neck dissection, or gross injury to the neck that would pre-clude reasonable surgical dissection for this trial, or radiotherapy to the neck.
6. The patient is actively receiving systemic cytotoxic chemotherapy.
7. The patient is on immunosuppressive, anti-monocyte, or immunomodulatory therapy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2021

Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL71228.041.19