Assessment of contralateral cervical metastases using sentinel lymph node biopsy in patients with lateralized oral carcinoma and ipsilateral cervical metastasis: a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25346

Source
Nationaal Trial Register

Brief title
CONSENT study

Health condition

Oral cavity cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome of this prospective study is the rate of occult contralateral lymph node metastases in patients with lateralized oral cavity squamouss cell carcinoma, a clinically negative contralateral neck and a clinically ipsilateral positive neck.

Secondary outcome

• The incidence of contralateral drainage patterns, as assessed by means of 99mTc-nanocolloid lymphoscintigraphy, in patients with lateralized oral cavity squamous cell carcinoma, a clinically negative contralateral neck and clinical ipsilateral lymph node metastases.
• The incidence and degree of postoperative complications, graded by means of the Clavien-Dindo classification of Surgical Complications, in patients who underwent additional sentinel lymph node biopsy and patients who did not undergo additional sentinel lymph node biopsy and only underwent surgical tumor resection and ipsilateral neck dissection.
• The duration of hospital stay in days in patients who underwent additional SLNB and patients who did not undergo additional sentinel lymph node biopsy and only underwent surgical tumor resection and ipsilateral neck dissection
• Tumor specific data (i.e. clinical TNM-staging, size and site of the primary tumor, distance from the midline of the primary tumor, depth-of-invasion of the primary tumor, histopathological grading of the primary tumor, perineural and lymphovascular invasion of the primary tumor, amount of ipsilateral cervical lymph nodes containing metastases, location of cervical lymph nodes containing metastases and presence of extranodal growth of lymph node metastases) will be obtained from electronical health records.

Study description

Background summary

Rationale: 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.
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, 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, 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.
Study population: 26 patients with lateralized OSCC, without midline involvement, a clinically negative contralateral neck and clinically ipsilateral lymph node metastasis, scheduled for tumor resection and ipsilateral neck dissection will be studied.
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).
Main study parameters/endpoints: 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

We hypothesize that the incidence rate of contralateral lymph node metastases in patients with lateralized oral cavity squamous cell carcinoma, clinical ipsilateral metastases and a contralateral clinically negative neck is equal or higher than reported in literature (mean 8% [95%CI 3.7-12.4%]) and that these contralateral lymph node metastases can reliably be detected with sentinel lymph node biopsy, allowing for more individualized management of the contralateral neck.

Study design

Preoperative lymphoscintigraphy, postoperative histopathological results, follow-up (1-year and 2-year).

Intervention

Sentinel lymph node biopsy

Contacts

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Eligibility criteria

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) 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 negative 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 (Appendix 4: Performance Status Criteria).

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 following anatomical areas: non-mobile base of the tongue, oropharynx, nasopharynx, hypopharynx, 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 10 days (240 hours) of injection.
5. The patient has a history of neck dissection, or gross injury to the neck that would preclude 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2020
Enrollment:	27
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-01-2020
Application type:	First submission

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
NTR-new	NL8322
Other	METC UMC Utrecht : METC 19-686

Study results