Sentinel lymph node detection in early-stage oral cavity squamous cell carcinoma using computed tomographic lymphography

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28606

Source
Nationaal Trial Register

Brief title
SELECT

Health condition

Early-stage oral cavity squamous cell carcinoma

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Diagnostic accuraccy, in terms of sensitivity and negative predictive value, of CT

lymphography for detection of sentinel lymph nodes in early-stage oral cavity squamous cell carcinoma.

Secondary outcome

• Preoperative sentinel lymph node detection rate using CT lymphography as compared to conventional lymphoscintigraphy.
• Preoperative higher echelon node detection rate using CT lymphography as compared to conventional lymphoscintigraphy.
• To compare histopathologic assessment (presence or absence of metastasis) of the excised lymph node(s) detected by conventional preoperative 99mTc-nanocolloid lymphoscintigraphy and intraoperative gammaprobe localization, with the sentinel lymph nodes identified by means of preoperative CT lymphography.
• Observing contralateral drainage patterns in lateralized tumors and compare these patterns between CT lymphography and conventional 99mTc-nanocolloid lymphoscintigraphy.
• To assess pairwise inter-observer agreements between CT lymphography and conventional 99mTc-nanocolloid lymphoscintigraphy regarding preoperative sentinel lymph node detection.

Study description

Background summary

Rationale: Cervical lymph node metastasis is the single most important prognostic factor in head and neck squamous cell carcinoma (HNSCC), including oral cavity squamous cell carcinoma (OSCC), and accurate detection of cervical lymph node metastases is critical for surgical and adjuvant therapy planning and prognosis prediction. The sentinel lymph node (SLN) procedure is a diagnostic staging procedure that is applied in a variety of tumour types, including HNSCC. The SLN is the first draining lymph node from the tumor, which is most likely to harbour metastases. The histopathological status of the SLN should reflect the histopathological status of the rest of the nodal basin, and additional treatment of the nodal basin (e.g., surgery) should be performed in case of metastatic involvement of the SLN. Detecting SLNs close to tumor sites is hampered, since the injection site of the radiotracer, around the primary tumor, produces a large hotspot on lymphoscintigraphy possibly hiding SLNs in close proximity of the primary tumor (‘shine through’ effect). SLN imaging using CT techniques might be more sensitive for detection of SNLs.
Objective: The primary objective of this study is to assess the diagnostic accuracy, in terms of sensitivity and negative predictive value, of preoperative CT lymphography as compared with conventional lymphoscintigraphy for SLN detection. Secondly, we aim to assess the diagnostic accuracy of preoperative CT lymphography combined with conventional preoperative lymphoscintigraphy for SLN detection.
Study design: 1. A pilot study to optimize the CT lymphography imaging protocol and build experience with the outcomes of CT lymphography (10 patients).
2. A prospective cohort study and a within-patient evaluation of CT lymphography for

identification of SLNs as compared to conventional 99mTc- nanocolloid lymphoscintigraphy in patients with early-stage OSCC (84 patients).
Study population: A total of 94 patients (age ≥ 18 years) with early-stage OSCC (T1-3, cN0, M0) scheduled for transoral excision and SLN biopsy will be included in this study.
Main study parameters/endpoints: The sensitivity and negative predictive value of CT lymphography as compared with conventional lymphoscintigraphy for SLNB. In addition, the sensitivity and negative predictive value for preoperative CT lymphography combined with conventional preoperative lymphoscintigraphy.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will undergo an additional CT lymphography after peritumoral injections with lipiodol. The information obtained by CT lymphography may provide helpful anatomical information of the SLN(s) for the surgeon, which may help in harvesting the SLN(s), especially in cases where the SLN(s) are located close to the injection site of the primary tumor. The extra administration of 0.5 mL lipiodol, followed by CT imaging, will not result in a significant additional (radiation) burden for the patient.

Study objective

It is hypothesized that CT lymphography, in combination with conventional lymphoscintigraphy, can more accurately identify sentinel lymph nodes and can therefore bring SLNB for all subsites of OSCC to a higher level (i.e. sensitivity ≥0.86).

Study design

- 1 day before surgery
- Day of outcome of histopathological assessment
- Follow-up according to standard of care for at least 48 months.

Intervention

CT lymphography following peritumoral administration of 0.5mL lipiodol.

Contacts

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Eligibility criteria

Inclusion criteria

1. The patient has provided written informed consent authorization before participating in the study.
2. The patient has a diagnosis of primary oral squamous cell carcinoma that is anatomically located in: mucosal lip, buccal mucosa, lower alveolar ridge, upper alveolar ridge, retromolar gingival (retromolar trigone), floor-of-the-mouth, hard palate or oral (mobile) tongue, and is stage T1-T2 and T3 (only when T3 is assessed based on tumour dimensions of >2 cm and ≤4 cm with DOI >10 mm), N0, M0 (see Appendix 4: TNM Staging).
3. Clinical nodal staging (N0) has been confirmed by negative results from ultrasound guided fine needle aspiration cytology.
4. The patient is a candidate for transoral excision and sentinel lymph node biopsy.
5. The patient has given informed consent for a surgical procedure regarding his/her oncological treatment.
6. Patients with prior malignancy of 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 and no evidence of recurrence.
7. The patient is ≥8 years of age at the time of consent.
8. The patient has an ECOG status of Grade 0 – 2 (see Appendix 5: Performance Status Criteria).

Exclusion criteria

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. Patient is incapacitated.
3. Patient is pregnant or lactating.
4. Previous allergic reaction after administration of a CT-contrast-agent for contrast enhanced CT-imaging.
5. Patient is known with manifest hyperthyroidism.
6. The patient has clinical or radiological evidence of metastatic cancer to the regional lymph nodes.
7. 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.
8. The patient is actively receiving systemic cytotoxic chemotherapy.
9. Patient is on immunosuppressive, anti-monocyte, or immunomodulatory therapy.
10. Participation will result in unacceptable delay regarding oncological treatment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	94
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-10-2020
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	NL9005
Other	METC University Medical Center Utrecht : METC 20-079

Study results