Sentinel lymph node detection in early-stage ORal Cavity squamous cell carcinoma using Magnetic Resonance (MR) lymphogrAphy

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The primary objective of this feasibility study is to investigate the detection rate of SLNs using MR lymphography.

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

Summary

ID

NL-OMON49901

Source
ToetsingOnline

Brief title
ORCA

Condition

- Head and neck therapeutic procedures

Synonym
Oral 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: Lymphography, MRI, Oral cancer, Sentinel node

Outcome measures

Primary outcome

The main study parameter will be the detection rate of sentinel lymph nodes with MR lymphography compared to conventional sentinel lymph node scintigraphy using 99mTc-nanocolloid.

Secondary outcome

• To compare the number of MR lymphographic detected SLNs with those detected by means of 99mTc-nanocolloid lymphoscintigraphy on a per-subject basis.

• 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 SLNs identified by means of preoperative MR lymphography.

• Observing contralateral drainage patterns in lateralized tumors and compare these patterns between MR lymphography and conventional 99mTc-nanocolloid lymphoscintigraphy.

• To assess pairwise inter-observer agreements between MR lymphography and conventional 99mTc-nanocolloid lymphoscintigraphy regarding preoperative SLN detection.

Study description

Background summary

Cervical lymph node metastasis is the single most important prognostic factor in 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) 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 of SLNs close to tumor sites is hampered in procedures using 99mTc-nanocolloids due to injection site (around the primary tumor) producing a large hotspot on lymphoscintigraphy possibly hiding SLNs in the close proximity of the primary tumor (''shine through''). Sentinel lymph node imaging using MRI techniques might be more sensitive for detection of SLNs.

Study objective

The primary objective of this feasibility study is to investigate the detection rate of SLNs using MR lymphography.

Study design

The proposed feasibility study is a within-patient evaluation of MR lymphography for identification of sentinel lymph nodes in early stage oral cavity carcinoma and compared imaging results to lymphoscintigraphy using 99mTc-nanocolloid with histopathology as the reference standard.

Study burden and risks

Patients will undergo an additional MR lymphography with a duration of 30 minutes after receiving peritumoral injections with gadolinium-based contrast agent. The additional anatomical imaging with MRI might lead to additional detection of sentinel lymph nodes without the radiation burden that is necessary for 99mTc-nanocolloid SPECT-CT imaging that is routinely performed. The extra administration of gadolinium-based contrast agend, followed by MR imaging, will not result in a significant additional (radiation) burden for the patient.

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

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 tumor dimensions of >2 cm and <=4 cm with DOI >10 mm), N0, M0 (see Appendix 3: TNM Staging).
3. Clinical nodal staging (N0) has been confirmed by negative results from CT, MRI, PET/CT and/or ultrasound guided fine needle aspiration cytology within 30 days of the SLNB procedure.
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 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 >=18 years of age at the time of consent.
8. The patient has an ECOG status of Grade 0 - 2 (see Appendix 4: 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. The patient is pregnant.
3. Patient is incapacitated.
4. Previous allergic reaction after administration of a gadolinium-based contrast agent for contrast enhanced MR imaging.
5. The patient has clinical or radiological evidence of metastatic cancer to the regional lymph nodes.
6. 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.
7. The patient is actively receiving systemic cytotoxic chemotherapy.
8. Patient is on immunosuppressive, anti-monocyte, or immunomodulatory therapy.
9. Patient has severe renal impairment (eGFR<30).
10. Participation will result in unacceptable delay regarding oncological treatment.
11. Patients with known claustrophobia, who are as a consequence unable to undergo MR imaging.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Not applicable
Generic name:	Gadovist

Ethics review

Approved WMO Date:	27-10-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-12-2021
Application type:	First submission
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
EudraCT	EUCTR2021-003554-23-NL
CCMO	NL78145.041.21