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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25346

Bron
Nationaal Trial Register

Verkorte titel
CONSENT study

Aandoening

Oral cavity cancer

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Sentinel lymph node biopsy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-02-2020
Aantal proefpersonen:	27
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8322
Ander register	METC UMC Utrecht : METC 19-686

Resultaten