Analyse van de lymfatische drainage in de hals bij mondholte tumoren door het gebruik van ICG-nanocolloid.

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Via a peritumoral injection of ICG-nanocolloid, lymphatic mapping of oral cavity tumors can be performed

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

Samenvatting

ID

NL-OMON23645

Bron
NTR

Verkorte titel
Oral cavity lymphatic mapping using ICG-nanocolloid

Aandoening

Oral cavity carcinoma; Squamous cell carcinoma; Head and Neck cancer, Tongue cancer, Floor of mouth cancer

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Plesmanlaan 121, 1066 CX, Amsterdam, the Netherlands

Overige ondersteuning: The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Amsterdam, the Netherlands, Division HOD

NWO-STW-VIDI (Grant No. STW BGT11272)

ERC-starting Grant (Grant No. 2012-306890)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Lymphatic mapping of the neck in oral cavity malignancies using ICG-nanocolloid.

Toelichting onderzoek

Achtergrond van het onderzoek

In 20-30% of the patients with squamous cell carcinoma of the oral cavity who are staged clinically node negative occult metastasis are present. In experienced hands, the most sensitive method of staging the lymph nodes of the neck is ultrasound-guided fine needle aspiration cytology (USgFNAC) with a sensitivity and specificity of 42-98% and 92-100%, respectively. To further improve the sensitivity of occult lymph node metastasis detection, patients with USgFNAC negative lymph nodes are generally scheduled for a sentinel node (SN) biopsy procedure.

The SN is defined as a lymph node receiving direct lymph drainage from the primary tumor. Assuming the orderly spread of tumor cells through the lymphatic system, pathological evaluation of the SN allows accurate determination of the tumor status of the lymph node and therefor the regional lymphatic system.

Some authors have stated that the tumor load of the lymph nodes can influence the drainage route of the radiocolloid through the lymphatic system in such a way that lymph nodes saturated with tumor deviate the drainage pattern. This may ultimately lead to the identification of a different SN than the true tumor-harboring node SN. This phenomenon is called “rerouting”. Another phenomenon that can influence the false-negative rate in are the so-called “skip metastases”. The term “skip metastases” refers to the presence of lymph node metastasis in the lower neck levels (levels III-V) whereas the level I and II lymph nodes (more close to the tumor) are metastasis free. Byers et al. reported that “skip metastases” are present in 16% of tongue carcinoma patients.

Within this study we will investigate the drainage pattern of oral cavity tumors using an intraoperative injection of the colloidal tracer ICG-nanocolloid. Fluorescence imaging of this tracer allows use to study the above-mentioned primary and secondary study aims.

Doel van het onderzoek

Via a peritumoral injection of ICG-nanocolloid, lymphatic mapping of oral cavity tumors can be performed

Onderzoeksopzet

One timepoint, directly after excision of the neck dissection specimen fluorescent lymph nodes will be identified

Onderzoeksproduct en/of interventie

Directly before the start of the operation 0.4-0.8 mL ICG-nanocolloid will be injected around the primary tumor. After the therapeutic or elective neck dissection the fluorescent lymph nodes will be excised and photographed. This will be done per cervical level. Fluorescent lymph nodes will be collected separately from the lymph nodes collected with the neck dissection specimen. After completion of the operation, specimens will be sent to the department of pathology for evaluation of the tumor status of the nodes. Fluorescent lymph nodes will be evaluated following the sentinel node protocol. The remainder lymph nodes will be evaluated following the standard protocol.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients ≥ 18 years;

Patients with T1-T4 oral cavity tumor;

Patients scheduled for commando resection or transoral resection with a subsequent elective or therapeutic neck dissection.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who have received prior surgical treatment or radiation therapy to the neck;

Hyperthyroid or thyroidal adenoma;

History of iodine allergy;

Severe kidney insufficiency.

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:	01-07-2015
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2015
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	NL5087
NTR-old	NTR5219
Ander register	: N14LMN

Resultaten