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

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Primary aim:Lymphatic mapping of the neck in oral cavity malignancies using ICG-nanocolloid. Secondary aims:- Analysis of lymphatic drainage of the head and neck area to determine the extension of the neck dissection.- Identification of the tumor...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41880

Source
ToetsingOnline

Brief title
Lymphatic mapping of the neck using ICG-nanocolloid

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

Synonym
oral cavity carcinoma

Health condition

hoofd-hals oncologie: mondholtetumoren

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-STW-VIDI 11272; ERC-starting grant 50309

Intervention

Keyword: lymphangiography, oral cavity tumor, sentinel node

Outcome measures

Primary outcome

Identification of the lymphatic drainage pattern of oral cavity tumors

Secondary outcome

- Determination of the extension of the lymphatic drainage pattern.

- Identificaiton of tumor-postitive lymph nodes.

- Analysis of the rerouting phenomenon (in case lymph node metastasis are

found).

Study description

Background summary

In 20-30% of the patients with squamous cell carcinoma of the oral cavity who are staged clinically node negative occult metastasis are present.(1-3) In experienced hands, the most sensitive method of staging the lymph nodes (LNs) of the neck is ultrasound-guided fine needle aspiration cytology (USgFNAC) with a sensitivity and specificity of 42-98% and 92-100%, respectively.(4,5) To further improve the sensitivity of occult LN metastasis detection, patients with USgFNAC negative LNs are generally scheduled for a SN biopsy.
The SN is defined as a LN receiving direct lymph drainage from the primary tumor.(8) 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 LN and therefor the regional lymphatic system.

Some authors have stated that the tumor load of the LNs can influence the drainage route of the radiocolloid through the lymphatic system in such a way that LNs 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*.(14,15) 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 LN metastasis in the lower neck levels (levels III-V) whereas the level I and II LNs (more close to the tumor) are metastasis free. Byers et al. reported that *skip metastases* are present in 16% of tongue carcinoma patients.(16)

Study objective

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

Secondary aims:
- Analysis of lymphatic drainage of the head and neck area to determine the extension of the neck dissection.
- Identification of the tumor draining lymph node(s).
- In case of lymph node metastasis: Evaluation of the rerouting phenomenon.

Study design

In the operation room a peritumoral injection ICG-nanocolloid will be given after which the neck dissection will be performed. During the operation fluorescence imaging will be performed to evaluate if there are fluorescent lymph node present. Visualized fluorescent nodes will be collected after excision of the neck dissection specimen and sent in separately for pathological evaluation. Further inspection of the neck dissection specimen for the presence of fluorescent lymph nodes will be performed ex vivo. All lymph nodes will be sent to pathology for tumor status evaluation. Fluorescent lymph nodes will be analyzed following the SN protocol. Non-SNs will be evaluated following the normal pathology protocol.

Study burden and risks

At the NKI-AVL ICG-99mTc-nanocolloid is used as standard for SN biopsy procedures of head and neck malignancies. In this study we will use the non-radioactive counterpart, ICG-nanocolloid, to evaluate the tracer distribution from the tumor via the lymphatic system to the lymph node(s). This will be evaluated in 20 patients. Evaluation criteria are: 1) presence of fluorescent lymph nodes in the neck dissection specimen; 2) cervical level at which the fluorescent lymph node are found; 3) number of fluorescent lymph nodes per cervical level; 4) is there unilateral or bilateral drainage (most

important in case of unilateral tumors); 5) tumor status of the fluorescent lymph node(s); and 6) tumor status of non-fluorescent lymph nodes. In case of tumor metastases: 1) size of metastasis 2) size of lymph node in which the metastases is present.

Because ICG-nanocolloid is not radioactive, the surgeon/OR-personnel and patients will not suffer from radiation burden. To lower the pain burden for the patients, ICG-nanocolloid will be injected on the operation room when the patient is already under general anesthesia. Fluorescence evaluation of lymph nodes will be performed mainly ex vivo. Because of the intervention the patients will be 20-30 minutes longer under general anesthesia.

In rare cases intravenously injected ICG will lead to nausea, urticaria and anaphylactic shock (<1/10000). Because in this study a small amount of ICG will be injected peritumoral, the expectation is that the chance on side-effects is minimal.

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

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.

Exclusion criteria

Patients who have received prior surgical treatment or radiation therapy to the neck;
Hyperthyroid or thyroidal adenoma;
History of iodine allergy;
Severe kidney insufficiency.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	11-03-2015
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
CCMO	NL50506.031.14