Tracking of oral cavity carconomas in head and neck surgery

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49725

Source
ToetsingOnline

Brief title
Tracked oral cavity tumors

Condition

- Soft tissue neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym
oral cavity tumors

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: Electromagnetic navigation, Head and neck surgery, Oral cavity / tongue cancer, Tumor tracking

Outcome measures

Primary outcome

Accuracy of pointing to landmarks, these measurements will result in outcomes

where an accuracy in mm will be provided.

Secondary outcome

- assessment of the potential benefit of the navigation system in terms of

optimizing resection planes

- the assessment of the feasibility of intra-operative XperCT imaging to

preoperative images of the oral cavity for maxilla and mandible patients, and

3D US for tongue patients.

- evaluation of the intuitiveness of the newly introduced technique.

Study description

Background summary

Head and neck surgeons operate on a fine edge between radical resection of tumors and sparing of vital structures (e.g., arteries and nerves), visible only on specific preoperative scans (CT/MR). Identification of deep tumor margins inside the tongue is currently based on palpation and experience/expertise of the surgeon because reliable quantitative feedback is lacking. As a result positive and suboptimal resections are common. By means of image-guided surgery, we can navigate the procedure by visualizing pre-operative planned MR and/or CT based 3D models and providing the surgeon with real-time feedback on the position of the surgical tool within this model and more important relative to the tumor margins. These innovations may allow to reduce both irradical resections and morbidity. This is the first study to use MR-based three-dimensional (3D) models of surgical resections for

intra-operative navigation in head and neck surgery.

Study objective

The objective of this feasibility study is to evaluate the clinical accuracy of an in*house developed electromagnetic (EM) navigation system in determining adequate resection margins during surgery for malignant oral cavity tumors and specifically tongue tumors. Ultimately we aim for an error of less than 5 mm in 80% of the completed procedures. In this phase the study will be counted successful if it can be proven that the navigation system is accurate for at least 60% of the completed procedures.

Study design

A feasibility study

Study burden and risks

No expected risks next to the additional radiation dose for the included patients are expected. A similar approach for abdominal surgery was evaluated in 50 patients (N13NAV) and no potential risks for patients were identified during the course of the study. The only task that will change is a maximal 30 minute delay in the surgery time necessary to perform intraoperative imaging (XperCT/US scan) and accuracy measurements.

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

- Age * 18
- Patients planned for surgery of tumors fixated to the maxilla or mandible and patients with tongue tumors(tumor size > T1)
- Treatment plan approved by the head and neck multidisciplinary oncology meeting
- Patients Provide written *informed consent*

Exclusion criteria

- Metal implants in the neck area that could disturb EM field, influence EM tracking or jeopardize image quality of XperCT images.
- non-palpable tongue tumor
- Pacemaker

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	11-05-2017
Enrollment:	68
Type:	Actual

Medical products/devices used

Generic name:	Navigation system
Registration:	No

Ethics review

Approved WMO Date:	27-03-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-01-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-02-2019
Application type:	Amendment
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	NL60004.031.17