An explorative study to assess novel measurement methods for evaluating speech and swallowing function in healthy volunteers and patients with tongue carcinoma (stage I-II)

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

Summary

ID

NL-OMON57291

Source
ToetsingOnline

Brief title
DICTIE-study

Condition

- Other condition

Synonym
oral cancer, Tongue cancer

Health condition

Anatomische en functionele verschillen voor en na chirurgische behandeling van tongkanker.

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Amsterdam UMC

Intervention

Keyword: MRI, Speech, Swallow, Tongue

Outcome measures

Primary outcome

In the first part of the study the main study parameter is the feasibility and repeatability of an advanced 3D-dMRI to depict speech and swallowing. In the second part of the study the main endpoint is the feasibility of 3D-dMRI, manofluorography, and OPG to detect differences in speech and swallowing function before and after surgery of tongue cancer.

Secondary outcome

N/A

Study description

Background summary

The goal of this study is to investigate novel measurement methods for detecting anatomical and functional differences in speech and swallowing before and after surgery of patients with a stage I-II tongue carcinoma. A better understanding of the consequences after surgery is required to provide optimal preoperative patient counselling and ultimately improve rehabilitation therapy. 3D dynamic MRI (3D-dMRI) is a promising technique to gain more insight into speech and swallowing function. In addition, relatively new techniques, such as manofluorography, which is a videofluoroscopy swallowing study (VFSS) combined with high-resolution impedance manometry (HRIM), and optopalatography (OPG) offer new avenues for assessing speech and swallowing. The integration and

evaluation of these multiple data sources can contribute to a better understanding of the anatomical and functional outcomes after surgery of tongue cancer.

Study objective

The first part of the study aims to depict speech and swallowing function with 3D-dMRI in healthy volunteers to establish a set protocol for use in patients. The second part of the study will investigate if anatomical and functional differences in speech and swallowing between pre- and post-surgery situations in patients with tongue cancer can be measured with 3D-dMRI, manofluorography, OPG, and questionnaires.

Study design

The first part with healthy volunteers has an exploratory study design. The second part with stage I-II tongue cancer patients is an explorative prospective observational one-group cohort study.

Study burden and risks

The burden and risks for the healthy volunteers in this study associated with the MRI measurements are negligible since these measurements are non-invasive and biologically not harmful. Their involvement plays a crucial role in providing data on the movements during speech and swallowing with unaffected anatomy. This is essential in establishing normal values that will serve as a reference point for the second part of the study with tongue cancer patients. The questionnaires, preoperative MRI scan, manofluorography are part of standard clinical care for tongue cancer patients and therefore no additional risks are associated with participation. Furthermore, no health risks are accompanied with OPG. The burden to the study mainly includes the time it takes to participate. There will be five extra visits for examinations that are not (yet) part of the standard care pathway: 1) preoperative OPG, 2) 3-months postoperative OPG, 3) 3-months postoperative MRI scan, 4) 1-year postoperative OPG and 5) 1-year postoperative MRI scan (see Figure 1). The added burden of the study is the addition of study sequences to the MRI investigation while performing speech and swallowing activities during the MRI scans, which will increase the necessary diagnostic MRI scan time by 10 to 15 minutes.
No direct benefit is expected for participating patients. However, the knowledge gained from this study will provide a greater understanding of tongue function, thereby enhancing comprehension of speech and swallowing abilities in patients. Eventually, this will lead to improvements in speech and swallowing therapy and counseling. In addition, with further optimization of dynamic MRI, it could serve as a favorable substitute for VFSS, eliminating the necessity for radiation in diagnosing swallowing function. Furthermore, outcomes of the current study could eventually contribute to a better trade-off in which part

of the tongue should be removed with the functional outcome considered and could thus provide a benefit for these patients in general. Ultimately, insights from this study may lead to optimized pre-operative patient information and a better focus in their rehabilitation therapy.

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

Healthy volunteers:
In order to be eligible to participate in this study, healthy volunteers will participate who are able to understand the research requirements and who will sign an informed consent form. The age of volunteers is between 18-80 years old at the time of signing the informed consent. To participate in this study, subjects must be able to read, speak and understand the Dutch language.

Patients:
In order to be eligible to participate in this study, a patient must meet all following criteria: patients over 18 years of age with newly diagnosed T1-T2 N0 squamous cell carcinoma of the tongue that will be planned for curative therapy, a partial glossectomy with primary closure or free flap reconstruction. To participate in this study subjects must be able to read, speak and understand the Dutch language, the participant information and the informed consent.

Exclusion criteria

Healthy volunteers:
Exclusion criteria are metal braces, dental splints, or any general MRI contraindication.

Patients:
A potential patient who meets any of the following criteria will be excluded from participation in this study:
- Postoperative radiation therapy
- ASA IV or V
- Absolute contraindications for MRI (e.g. pacemaker, ICD or surgery in the last 6 months)
- Orthodontic braces
- Pregnancy or potential pregnancy
- Claustrophobic or anxious during MRI
- Orthopnea
- Unable to lie down and lie still for 30 minutes

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-02-2024
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	NL82621.041.23