Personalisation of a biomechanical tongue model for the prediction of treatment outcome.

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The next step is to personalize the model and validate the model using different modalities. These modalities are grouped into four subprojects. Finally, the results of the subprojects will be integrated within the biomechanical model so that a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON45672

Source
ToetsingOnline

Brief title
Personalisation of a biomechanical tongue model.

Condition

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

Synonym
Tongue cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomechanical tongue model, Functional inoperabel, Tongue cancer, Virtual Therapy

Outcome measures

Primary outcome

A personalized prediction of functional consequences after treatment using a

biomechanical model of the tongue and tongue base.

Secondary outcome

Range of motion endpoints

* Range of tongue motion before and after operation.

* Additional questionnaires regarding tongue function (appendix)

* Tongue muscle strength (IOPI) before intervention

* Tongue muscle strength (IOPI) after intervention

Elastography endpoints

* Elasticity of tongue tissue before intervention

* Elasticity of scar tissue / irradiated tissue

MRI endpoints

* Tongue muscular anatomy before and after partial glossectomy

* Tongue functionality before and after partial glossectomy

Resection profile endpoints

* Dimensions of the resection intraoperatively.

* Dimensions of the specimen.

Study description

Background summary

Among all treatments of cancer, surgery of locally advanced head and neck cancer has one of the highest risks of loss of vital functions. Speech, mastication and swallowing are complex functions that are easily affected. A systematic review on swallowing dysfunction and speech intelligibility after oral cancer surgery demonstrated that serious swallowing deficiencies were experienced by over 80% of patients and severe impairment of speech intelligibility was observed in 20% of patients1. The term *functional inoperability* is used when unacceptable function loss after surgery is to be expected2,3. Organ-sparing chemoradiation for advanced oral cancer is used as an alternative to surgery, but this therapy can also seriously affect vital functions due to fibrosis and xerostomia4. The choice between these two treatment modalities is not evidence based. In an international survey among surgeons and radiotherapists no consensus was reached for the majority of surgical interventions regarding functional inoperability3. Objective counselling of patients on the expected functional outcome is therefore currently impossible. Although severely needed, no standardized evaluation tool exists to help predict a personalized functional outcome of oral cancer therapies. In the project *Virtual Therapy*, we are developing such a tool for oral cancer surgery and radiotherapy. Within the virtual therapy project (www.virtualtherapy.nl) we are developing a biomechanical model of the oral cavity to quantitatively predict function loss after treatment (virtual treatment).

The past couple of years we worked on biomechanical models of the lips and oral cavity in collaboration with the University of Twente and the University of British Columbia, which supplied us with a framework (ArtiSynth) to create and to edit biomechanical models (artisynth.magic.ubc.ca)5. The ArtiSynth framework is used to develop an advanced surgical simulation tool demonstrating postoperative movement after a partial glossectomy. click here for a video. A comparison between the postoperative movement of the model and three patients showed that the model was indeed able to show qualitative comparable motions6. This model was also able to simulate impairments as a result of fibrosis which occurs in both surgery and radiotherapy.

More details can be found in the additional protocol.

Study objective

The next step is to personalize the model and validate the model using different modalities. These modalities are grouped into four subprojects. Finally, the results of the subprojects will be integrated within the biomechanical model so that a completely personalized virtual partial glossectomy or radiotherapy treatment can be performed and the posttreatment impairment can be simulated

Study design

Prospective cohort study / Feasibility study

Study burden and risks

During the three visits the extent of burden will be
- Visit 1: 35 minutes
- Visit 2: 65 minutes (surgery patients) or 20 minutes (radiotherapy patients)
- Visit 3: 20 minutes

None of the procedures in this study are considered to be of any physical harm to the patient. No invasive measurements are performed.

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

Primary tongue or tongue base cancer (T1-T3).
Primary surgery or chemoradiation treatment.
Older than 18 years
Informed consent

Exclusion criteria

Previous history of oral or oropharyngeal cancer
Recurrent or residual tongue/tongue base cancer
Patients that are not eligible for MRI

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	30-06-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	27-10-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL60608.031.17