Active and passive elasticity measurements of the tongue using in vivo measurement techniques

Published: 18-07-2018
Last updated: 12-04-2024

The primary objectives of this study are:* Analyse if shear wave ultrasound elastography with ElastQ and LASTIC are both feasible techniques to identify differences in tongue tissue elasticity and analyse if there is a correlation between both...

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

Summary

ID

NL-OMON46444

Source
ToetsingOnline

Brief title
Active and passive elasticity measurements of the tongue

Condition

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

Synonym
Tongue carcinoma

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: ElastQ, LASTIC, Shear wave ultrasound elastography, Virtual Therapy

Outcome measures

Primary outcome

Group 1:

* (Active) Elasticity of left and right side of the tongue measured by two

observers.

Group 2 before GA:

* Active component of tongue muscle elasticity

Group 2 during GA:

* Passive component of tongue muscle elasticity

Secondary outcome

Modify biomechanical model of the tongue with patient specific elastic

properties

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. The term *functional inoperability* is used when unacceptable function loss after surgery is to be expected. It is hard to reach a consensus for the majority of surgical interventions regarding functional inoperability. Making effective patient counselling on the expected outcome impossible. To make a better prediction of functional loss after treatment a project was launched called

Virtual Therapy. This project aims to develop a biomechanical model to simulate different treatment options and predict functional outcome on founded expectation. To make this model as accurate patient specific as possible, it is important to have knowledge of elastic properties of tissues in the oral region, e.g. the tongue. Elastic properties of the tongue are strongly influenced by postoperative fibrotic changes. but before we can say anything about the effects of fibrosis in patients we need to measure the passive and active stiffness of healthy tongue tissue. Shear wave ultrasound elastography and LASTIC are promising techniques to measure in vivo tissue elasticity.

Study objective

The primary objectives of this study are:
* Analyse if shear wave ultrasound elastography with ElastQ and LASTIC are both feasible techniques to identify differences in tongue tissue elasticity and analyse if there is a correlation between both techniques.
* Investigate if shear wave ultrasound elastography and/or LASTIC can be used to distinguish the *active* and * passive* component of the tongue muscle elastic properties.

Study design

Prospective feasibility study

Study burden and risks

No risks are expected with any of the interventions performed in this research protocol. The measurement for the active component of tongue stiffness takes up to twenty minutes and will be scheduled on a moment that is most suitable for the patient. The passive component measurement will be performed under general anaesthesia.

The risk of possible tissue damage with LASTIC has been reduced to a very minimum. Several articles describe that human cells and tissue will be damaged after applying 50% or more strain to the tissue for 5-10 minutes.. To set the strain limit on 50% and only applying it for a few seconds we assure no damage to the tissue will be done. If the volunteer experiences pain and wants to terminate to measurement all pressure can be released with the turn of one valve to assure direct and safe removal of the suction cup.

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

-older than 18 years
-informed consent

Exclusion criteria

- Pathologies or impaired functionality in the oral cavity and oropharynx region.
- Use of Laryngeal mask airway
- Unforeseen practical problems that make it impossible to carry out the measurements before the start of surgery.
- Chin not accessible with ultrasound sound probe, e.g. excessive amount of facial hair.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	38
Type:	Anticipated

Medical products/devices used

Generic name:	LASTIC
Registration:	No

Ethics review

Approved WMO Date:	18-07-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL64588.031.18