Shear wave ultrasound elastography of the tongue * a feasibility study.

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The primary objective of this study is to investigate how treatment affects tissue elasticity and to what extent those effects vary in patients. The secondary objective is to link elasticity to tongue muscle strength and to functional outcome.

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

Summary

ID

NL-OMON45577

Source
ToetsingOnline

Brief title
Shear wave ultrasound elastography 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: ElastPQ, Shear wave ultrasound elastography Tongue, Virtual therapy

Outcome measures

Primary outcome

Group 1 (Partial glossectomy patients)

* Elasticity of operated side/scar tissue

* Elasticity of tongue tissue contralateral to operational side (healthy tissue)

Group 2 ((chemo)radiation patients)

* Elasticity of tongue tissue that received the highest dose [Gray]

* Elasticity of tongue tissue that received the lowest dose [Gray]

Group 3 (healthy volunteers)

* Elasticity of left side tongue tissue

* Elasticity of right side tongue tissue

Secondary outcome

Group 1 (Partial glossectomy patients)

* Tongue muscle strength operated side/ scar tissue

* Tongue muscle strength of tongue tissue contralateral to operational side

(healthy tissue)

Group 2 ((chemo)radiation patients)

* Tongue muscle strength of tongue tissue area that received the highest dose

[Gray]

* Tongue muscle strength of tongue tissue area that received the lowest dose

[Gray]

Group 3 (healthy volunteers)

* Tongue muscle strength of left side tongue tissue

* Tongue muscle strength of right side tongue tissue

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. Organ-sparing chemoradiation for advanced oral cancer is used as an alternative to surgery. The choice between these two treatment modalities is not evidence based. Elastic properties of the tongue are strongly influenced by postoperative and post radiation fibrotic changes. Therefore fibrosis and other effects on tissue elasticity should be studied closely. Shear wave ultrasound elastography is a method to measure tissue elasticity.

Study objective

The primary objective of this study is to investigate how treatment affects tissue elasticity and to what extent those effects vary in patients. The secondary objective is to link elasticity to tongue muscle strength and to functional outcome.

Study design

Prospective feasibility study

Study burden and risks

The extent of burden:
* Control visit at the radiology deparment for an ultrasound will be extended with 10 minutes.

This procedure is not considered to be of any physical harm to the patient.

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 cancer (T1-T4).
Primary surgery treatment or primary treatment with radiation therapy.
Patient should already have an appointment at the radiology department
Older than 18 years
Informed consent

Exclusion criteria

Patients:
Treatment for recurrent or residual tongue cancer
Location of tumour was on the tip of the tongue (not visible on US);Healthy volunteers:
History of oral cancer
History of other oral cavity diseases.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2017
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO Date:	11-05-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-09-2017

Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-01-2018
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	NL60754.031.17