

The Shrink Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22691

Source

NTR

Brief title

The Shrink Study

Health condition

Oral Squamous Cell Carcinoma (OSCC)

NL: Mondholtecarcinomen

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

To compare mucosal shrinkage (from in vivo to histopathological examination) in each arm

Secondary outcome

- Shrinkage from in-vivo to directly after resection

- Shrinkage from in-vivo to after formalin fixation
- To define a shrink factor for each resection modality, taking into account the individual energy settings used.

Study description

Study objective

While head and neck surgeons aim for a 1 cm healthy tissue margin during resection of OSCC, pathological examination often reveals a smaller margin. Our hypothesis is that this occurs due to shrinkage of mucosa following the resection and due to the process of preparation for pathological examination, including formalin fixation, paraffin embedding,

Intervention

Resection using thulium laser or monopolar electric knife

Contacts

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Eligibility criteria

Inclusion criteria

- >18 years old

- Confirmed OSCC stage I – IVa (OncoLine, 2004)
- ASA classification I and II

Exclusion criteria

- Previously operated/irradiated OSCC or other malignancy of the oral cavity.
- Stage IVb (inoperable disease)
- Co-morbidities resulting in disability to undergo surgery under general anesthesia
- Inability to sign informed consent
- impaired mental status

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date: 16-07-2014
Application type: First submission

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
NTR-new	NL4549
NTR-old	NTR4692
Other	: METC13-340

Study results

Summary results

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