"The Shrink Study: shrink factor of resected tumour mucosa in patients with oral squamous cell carcinoma"

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Investigate whether different resection modalities such as MO or TL cause a different amount of shrinkage in the mucosal margins of resected OSCCs.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41703

Source
ToetsingOnline

Brief title
The Shrink Study

Condition

- Soft tissue neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym
oral cancer, oral squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: monopolar electric surgery, oral cancer, shrink, thulium

Outcome measures

Primary outcome

The amount/percentage of mucosa shrinking for the two abovementioned resection

modalities (MO en TL), and hereby adjust margin interpretation method using

the energy used for the electric resection modalities.

Secondary outcome

not applicable

Study description

Background summary

Monopolar electro surgery (MO) and thulium laser (TL) are used for the resection of oral squamous cell carcinomas (OSCC). These electric modalities, MO and TL, have been evaluated at our Institution with regards to pathological assessment and effectiveness (namely radical resections). Adequate pathological assessment was possible when OSCCs were removed by MO or TL. Three times more irradical resections were present in the MO group compared with the TL group. Various factors were associated with the resection margins, such as non-cohesive growth and tumor size. Since both resection modalities cause thermal damage we question whether the MO causes more shrinkage of the resected tissue than TL, subsequently resulting in smaller resection margins. We expect that different resection modalities cause different shrinkage. Subsequently a *shrink factor* could be calculated for each resection method, which could be taken into account when interpreting resection margins and therefore could result in a different postoperative therapy advice.

Hypothesis: Resection of OSCCs with MO causes more shrinkage of mucosal tissue than resection performed with TL.

Study objective

Investigate whether different resection modalities such as MO or TL cause a

different amount of shrinkage in the mucosal margins of resected OSCCs.

Study design

Randomized controlled trial.

Intervention

Resection of oral cavity carcinoma with either a monopolar knife (MO) or thulium laser (TL)

Study burden and risks

All included patients are eligible for surgical resection of the diagnosed OSCC as primary treatment. All modalities used are standard methods of resection in our institution. Within this study the resection modality used for each patient will be randomized. The expected risk is as high as any otherwise performed surgical resection of OSCCs. Intra- and postoperative bleeding, infections and pain are standard risks. There is no direct benefit for any patient included in this study. A possible consequence of the study results is a change of margin interpretation after this study, possibly resulting in less aggressive postoperative treatment (for example radiotherapy) and therefore improvement in quality of life. These results will be evaluated in a bigger follow-up study after analysis of this pilot study.

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

> 18 years old
Confirmed OSCC stage I - IVa
ASA classification I, II and III

Exclusion criteria

Previously operated/irradiated in the field of surgery
Stage IVb
Physical status that is a contraindication for surgery in general anesthesia
Mental impairment ;note: In the rare case that the surgeon pre- or peroperatively finds that the randomized modality is not suitable for resection of a patients tumor, this patient will be withdrawn from the study and treated as the surgeon thinks suitable.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	02-05-2014
Enrollment:	76
Type:	Actual

Medical products/devices used

Generic name:	Thulium laser en monopolar electro surgery
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-04-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-09-2015
Application type:	Amendment
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	NL45789.041.13