Ultrasound guided resection of tongue and buccal mucosa cancer

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In last decades, ultrasound probes have become smaller, which made adequate intraoral ultrasound of oral tumors possible. Therefore, invasion depth is now determined pre-operatively by intraoral ultrasound for staging of oral cancer. Our feasibility…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55827

Source
ToetsingOnline

Brief title
TRUST

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
buccal mucosa cancer, tongue cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: 7T MRI, intraoral, tongue cancer, ultrasound

Outcome measures

Primary outcome

resection margin control

Secondary outcome

amount of re-resections or postoperative irradiation.

Study description

Background summary

Squamous cell carcinoma of the tongue and buccal mucosa is preferably treated by surgery. Its complete removal is essential for locoregional control and disease-free survival. Inadequate resection margins require adjuvant therapy such as re-resection or (chemo)radiation, which causes extra morbidity. Unfortunately, resection margins in tongue and buccal mucosa cancer are often inadequate and the main indication to apply adjuvant treatment in these patients. A retrospective analysis of surgically treated patients with tongue and buccal mucosa squamous cell carcinoma in our centre revealed 51-70% close margins and 15-24% positive margins in our center. Especially deep resection margins often appeared close or positive. These results are in line with literature, that reports 42-48% close resection margins and even 28-36% positive resection margins in oral cancers. Adjuvant treatment at the primary tumor site was given to 31-35% of our patients with oral cancer (re-resections or radiotherapy) which could have been prevented by better margin control. Adjuvant treatment (especially irradiation) after inadequate resection may affect the quality of life of our patients due to significant morbidity and (oral) discomfort, including xerostomia, mucositis, fibrosis and osteoradionecrosis. To reduce morbidity in patients with tongue and buccal mucosa cancer, better control of submucosal and deep resection margins is pivotal.

Study objective

In last decades, ultrasound probes have become smaller, which made adequate intraoral ultrasound of oral tumors possible. Therefore, invasion depth is now determined pre-operatively by intraoral ultrasound for staging of oral cancer.

Our feasibility study of ultrasound guided resection of tongue cancer revealed a improvement of margin control without resection of an excessive amount of healthy tissue.

Objective
We aim to use intraoral ultrasound during resection of tongue and buccal mucosa squamous cell carcinomas to limit the amount of close and positive resection margins and reduce the amount of re-resections or postoperative irradiation and thereby reduce morbidity to eventually improve the quality of life of our patients.

Study design

1. A feasibilty study to optimize the protocol and built experience (learning curve) with imaging guided surgery for early tongue cancers using intraoral ultrasound. (10 patients), finished in February 2020,
2. A pilot study in tongue cancer to investigate if ultrasound guided resection improves margin control (30 patients)
3. A pilot study in buccal mucosa cancer to investigate if ultrasound guided resection improves margin control (25 patients)

Intervention

ultrasound guided resection of tongue or buccal mucosa cancer.

Study burden and risks

Burden and risks are minimal, since ultrasound are a non-invasive form of imaging.

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

tongue cancer or buccal mucosa cancer with indication of surgical resection

Exclusion criteria

none

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2019
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-09-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-06-2021
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	NL69038.041.19