Ultrasound-guided resection of buccal mucosal carcinomas - a multicenter study

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The aim of this research is to decrease the number of involved margins, resulting in less adjuvant therapy and less local recurrences.

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

Summary

ID

NL-OMON53333

Source
ToetsingOnline

Brief title
BRUG

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
buccal mucosal cancer, oral cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Buccal mucosa cancer, Intraoral, multicenter study, Ultrasounds

Outcome measures

Primary outcome

Number of involved margins (<1 mm).

Secondary outcome

The accuracy of the ultrasound for measuring tumor thickness

Need for adjuvant therapy

The influence of treatment on the quality of life

Study description

Background summary

Buccal mucosa cancer is a rare disease. In the Netherlands, approximately 100 patients are treated for this disease each year. To obtain good local control, it is important that the histological distance from the tumor to the resection plane is 5 mm or more (tumor-free margin). If the tumor-free margin is smaller, such as close (1-5 mm) or involved (<1 mm) margins, there is usually an indication for adjuvant therapy. Now, the tumor-free margins in buccal mucosa cancer are often insufficient, so that a significant proportion of patients require adjuvant treatment (re-resection or radiotherapy). Postoperative radiotherapy can greatly reduce the quality of life due to the development of, for example, osteoradionecrosis, mucositis and fibrosis. During a re-resection it is often difficult to find the location of the insufficient margin. Ultrasound-guided resection can be used to visualize the tumor during surgery, in order to improve the tumor-free margins. Currently, the tumor-free margin is only estimated palpably and frozen sections are sometimes used in case of doubt.

Study objective

The aim of this research is to decrease the number of involved margins, resulting in less adjuvant therapy and less local recurrences.

Study design

In this trial, 70 patients with a squamous cell carcinoma of the buccal mucosa will be included for treatment with ultrasound-guided resection. This is a prospective, non randomized trial.

Intervention

Ultrasound-guided resection of buccal mucosa carcinomas

Study burden and risks

Ultrasound is a non-invasive form of imaging with no harmful effect. The use of ultrasound during surgery might lead to more removal of healthy tissue, however, this may lead to less involved margins and adjuvant therapy. The anesthesia time will last 5-10 minutes longer. Furthermore, on 4 timepoints (before the operation and 3x in the year after operation) questionnaires will be send.

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
- Tumors of the buccal mucosa
- Histologically proven squamous cell carcinoma
- Whole tumor can be visualized by ultrasound
- Surgical removal under general anesthesia

Exclusion criteria

- Tumor is located in the retromolar areas

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2023
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-10-2023
Application type:	First submission
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
ClinicalTrials.gov	NCT05852665
CCMO	NL83714.041.23