UltraSound-guided resection of tongue cancer - Multicenter

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A relatively new method to determine margin distance is intraoral resection with a small Ultrasound (US)-probe. US is already used to determine tumor-thickness in tongue cancer preoperatively, because of its high predictive value. Four previous...

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

Summary

ID

NL-OMON52140

Source
ToetsingOnline

Brief title
MultiTRUST

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
oral 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: Intraoral, Multicenter study, Tongue cancer, Ultrasound

Outcome measures

Primary outcome

More free surgical margins.

Less local adjuvant trearment (re-resection or irradiation).

Better quality of life.

Secondary outcome

Better head and neck function.

Better cost-efficiency.

Study description

Background summary

Tongue cancer is preferably treated by surgical resection. Free margins (>=5 mm) are essential for local control. In case margins are close (1-5 mm) or positive (<1 mm), adjuvant treatment, i.e. a re-resection or (chemo)irradiation, is often indicated. Postoperative irradiation can have a serious effect on quality of life due to significant morbidity and (oral) discomfort (i.e. mucositis, fibrosis and osteoradionecrosis). In case of re-resections, relocating close or positive margins based on histopathological data is challenging. Moreover, it increases healthcare costs. Recently, a historical cohort of patients surgically treated for pT1-pT3 tongue cancer in the UMC Utrecht was analyzed. It revealed that only 18% patients had free resection margins. As a result, 30% of the patients had local adjuvant treatment, 9% re-resection and 21% irradiation.

To improve local control and to reduce adjuvant treatment, there is a need for a method that provides intra-operative feedback about the distance between the tumor and resection plane (margin distance). At the moment, this distance is estimated by palpation. In case the distance is doubted, frozen sections are used to investigate resection margins intraoperatively. However, this method is only usable to identify positive margins and clarifies little about the margin distance. The low sampling rate results in a low sensitivity in predicting

close or positive margins.

Study objective

A relatively new method to determine margin distance is intraoral resection with a small Ultrasound (US)-probe. US is already used to determine tumor-thickness in tongue cancer preoperatively, because of its high predictive value. Four previous clinical studies applied US during tongue cancer resections with favorable results. Interim analysis of our pilot study showed that ultrasound (US)-guided tongue cancer resections resulted in 55% free margins and reduction of the need for local adjuvant treatment (10% re-resection and 10% irradiation). To apply this technique in standard clinical care, it should be validated that intraoperative US-guided tongue cancer resection improves local control and that it reduces the need for adjuvant treatment, especially additional (chemo)irradiation. Additionally, it must be validated that US-guided resections leads to more quality of life, more head-and neck function and a better cost-efficiency than conventional surgery

Study design

A randomized controlled trial of 75 patients in both arms (150 in total). 75 patients will receive US-guided resections (treatment group), while other patients will receive conventional treatment. Patients will receive questionnaires (GRIX, SHI, SWAL-QOL (all centres) and EORTC - QLQ C30, EORTC QLQ HN35, E5D5L (only UMC Utrecht, Haaglanden MC, UMC Groningen, Erasmus MC and Medisch Spectrum Twente) this will take place one time before surgery and three times (3, 6 and 12 months) after surgery. Additionally, with the same timing, functional tests according to FROG (Functional Rehabilitation Outcome Grade) will be taken, however this will be only conducted in het UMC Utrecht.

At the included patients at the participating centers that allready assess the questionnaires EORTC QLQ30, EORTC H&N35, EQ5D5L as a clinical standard (i.e. Rijnstate, Radboud and AVL), will be informed that the data from these questionnaires will be used for the multiTRUSt study.

Intervention

US-guided resections of tongue cancer.

Study burden and risks

US is a non-invasive imaging method without harmfull effects.
Usage of US might result in more resection of healthy tongue tissue. However, there is a high potential on more free margins.
Time under narcosis will be elongated by 5-10 minutes.
Filling in questionnaires might be cognitively/emotionally exhausting for some

patients.
Testing patients on head-and neck function might be physically exhausting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Tongue cancer with indication of surgical resection under general anesthaesia.
Tumor is detectable as echolucent region on ultrasound.

Exclusion criteria

T4a tumours according to TNM 8th edition.

Patients treated earlier for tongue cancer.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2022
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-12-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-05-2022
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	08-09-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-01-2025
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	NL76681.041.21
Other	NL8336