

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Intraoperative intraoral sonography for tumor margin determination in T1-T2-T3 tongue cancer

#### Protocol summary

##### Summary

To assess the effectiveness of intraoperative intra oral sonography for adequate margin resection of tongue cancer, in a semi experimental clinical trial we divided patients in two groups. in one group the tumor resection during surgery is done by conventional method, the surgeon palpated the tumor margins and with 1-1.5 cm margin resect the tumor. in other group the surgeon uses intraoral sonography to determine the tumor margins, in this method tumor is seen hypoecho. with needle we can mark the tumor margin and then resect it.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111030811N1**  
Registration date: **2017-04-04, 1396/01/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-04, 1396/01/15

##### Registrant information

##### Name

Ebrahim Karimi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6670 6106

##### Email address

ebkarimi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

non

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Intraoperative intraoral sonography for tumor margin determination in T1-T2-T3 tongue cancer

##### Public title

intraoperative intraoral sonography for tongue cancer resection

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients who have oral cancer stage T1-T2-T3

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **32**

##### Randomization (investigator's opinion)

Not randomized

##### Randomization description

##### Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Tehran University of Medical Sciences Ethics committee

#### Street address

Tehran University of Medical Sciences, Keshavarz boulevard

#### City

Tehran

#### Postal code

1417653761

### Approval date

2016-10-08, 1395/07/17

### Ethics committee reference number

IR.TUMS.MEDICINE.REC. ۱۳۹۵.۷۱۷

## Health conditions studied

1

### Description of health condition studied

Tongue cancer

### ICD-10 code

C02

### ICD-10 code description

Malignant neoplasm of other and unspecified parts of tongue

## Primary outcomes

1

### Description

Surgical margin

### Timepoint

intraoperative

### Method of measurement

positive or negative in pathology report

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intraoperative intraoral sonography for tongue cancer resection

### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Amiralam hospital

#### Full name of responsible person

Mahdokht sadat Manavi

#### Street address

Tehran-Darvazeh Dowlat

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Masoud Younesian

#### Street address

Qods street, Keshavarz boulevard

#### City

Tehran

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Tehran University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mahdokht sadat Manavi

#### Position

Otolaryngology resident

**Other areas of specialty/work**

**Street address**

Darvazeh Dowlat

**City**

Tehran

**Postal code**

**Phone**

+98 21 6670 8103

**Fax**

**Email**

mahdokht\_mnv@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahdokht sadat Manavi

**Position**

Otolaryngology resident

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00

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**Email**

mahdokht\_mnv@yahoo.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*