

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of Surgical Outcomes of Endoscopic and Microscopic Surgery in Patients diagnosed as Otosclerosis Disease

#### Protocol summary

##### Study aim

Comparison of Surgical Outcomes of Endoscopic and Microscopic Surgery in Patients diagnosed as Otosclerosis Disease (Success of surgery, Duration of surgery, Complications)

##### Design

Two arm parallel group randomised clinical trial design of 62 patients; with method of Foursquare blocks, with out blinded outcome assessment.

##### Settings and conduct

In this study, Patients who are diagnosed as Otosclerosis Disease in Imam Khomeini Hospital between 2020 to 2021 are divided randomly into two groups. One group undergo Endoscopic surgery and the other group undergo Microscopic surgery.

##### Participants/Inclusion and exclusion criteria

Entry Requirements: Patients with a possible diagnosis of Otosclerosis  
Exit Conditions: History of previous Otologic Surgery-External Auditory Canal Stenosis below 8 mm

##### Intervention groups

First Group: Patients who have surgery through Endoscope. Eecond Group: Patients who have surgery through Microscope.

##### Main outcome variables

Endoscopic Otosclerosis Surgery has a higher success rate and fewer complications than the Microscopic method.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171004036554N3**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

##### Registration date

2021-01-06, 1399/10/17

##### Registrant information

###### Name

Hamed Emami

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2393

###### Email address

h\_emami@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-09, 1399/08/19

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Surgical Outcomes of Endoscopic and Microscopic Surgery in Patients diagnosed as Otosclerosis Disease

##### Public title

Comparison of Surgical Outcomes of Endoscopic and Microscopic Surgery in Patients diagnosed as Otosclerosis Disease

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Patients diagnosed as Otosclerosis Disease

### **Exclusion criteria:**

History of previous Otologic Surgery Revision Surgery for Otosclerosis External Auditory Canal Stenosis below 8 mm

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: **64**

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

Randomized

### **Randomization description**

The randomization type is blocked randomization. Foursquare blocks of intervention group(A) and control(B) are defined on cards 1-6 (AABB,ABAB,ABBA,BBAA,BABA,BAAB), the cards are placed inside the envelope. Then cards are selected randomly and then the random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence.

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

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

##### **Street address**

Vice Chancellor for Research and Technology,  
Keshavarz Boulevard Ghods St, Medical University of  
Tehran,

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

#### **Approval date**

2020-11-09, 1399/08/19

## **Ethics committee reference number**

IR.TUMS.AMIRALAM.REC.1399.021

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Otosclerosis Disease

#### **ICD-10 code**

H80

#### **ICD-10 code description**

Otosclerosis Disease

## **Primary outcomes**

### 1

#### **Description**

Audiologic Outcomes

#### **Timepoint**

Hearing Level at the beginning of the study and 2 months after surgery

#### **Method of measurement**

Audiology Test

### 2

#### **Description**

Post Operation Vertigo

#### **Timepoint**

First day after surgery

#### **Method of measurement**

VAS Test

### 3

#### **Description**

Post Operation Taste Disorder

#### **Timepoint**

2 months after surgery

#### **Method of measurement**

VAS Test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention Group: In this group surgery is performed using an Endoscope device that includes an Endoscopic Camera and Lens, through the Auditory Canal.

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Control Group: In this group surgery is performed using a Surgical Microscope. This procedure usually requires an incision behind the ear for better access during surgery.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr. Hamed Emami

**Street address**

Imam Khomeini Hospital, Dr.Qarib St, Khashavarz Blvd, Tehran

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hd-emami@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Sahraeian Mohammad Ali

**Street address**

corner of Quds Street, Keshavarz Blvd

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resdeputy@tums.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Yasaman Nemati

**Position**

Otolaryngologists, Resident at Tehran University of Medical Sciences

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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yasaman.nemati90@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**

Dr Hamed Emami

**Position**

Otolaryngologists, Assistant Professor at Tehran University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Hamed Emami

**Position**

Otolaryngologists, Assistant Professor at Tehran  
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**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Province**

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**Postal code**

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available