

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. Four square 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

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corner of Quds Street, Keshavarz Blvd

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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

Street address

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yasaman.nemati90@yahoo.com

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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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Name of organization / entity

Tehran University of Medical Sciences

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Position

Otolaryngologists, Assistant Professor at Tehran
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Latest degree

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Other areas of specialty/work

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Street address

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Province

Tehran

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