

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Stapedotomy on Tinnitus in Patients with Otosclerosis

Protocol summary

Study aim

In this study we aim to assess the success of stapedotomy on reduction of tinnitus in patients with otosclerosis.

Design

Non-randomized clinical trial on 19 patients

Settings and conduct

Otolaryngology department. Imam Khomeini hospital complex, Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with otosclerosis with more than 30 dB of air-bone gap in latest pure tone audiometry; Presence of tinnitus in the same ear
Exclusion criteria: History of surgery in the same ear, superior semicircular canal dehiscence, Meniere's disease

Intervention groups

Patients with otosclerosis with concomitant tinnitus

Main outcome variables

Tinnitus Score based on patient VAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201021049093N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Mehrdad Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

Email address

mehrdadj82@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-13, 1399/07/22

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Stapedotomy on Tinnitus in Patients with Otosclerosis

Public title

Effects of ear surgery on Tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Otosclerosis with more than 30 dB of air-bone gap in pure tone audiometry Tinnitus in the same ear

Exclusion criteria:

Previous surgery in the same ear Superior semicircular canal dehiscence Meniere's Disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 19

Randomization (investigator's opinion)

N/A

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

Street address

Baqerkhan

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

TUMS.AMIRALAM.REC.1399.010

Health conditions studied

1

Description of health condition studied

Otosclerosis

ICD-10 code

H80

ICD-10 code description

Otosclerosis

Primary outcomes

1

Description

Tinnitus score

Timepoint

Before and 6 months after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with conductive hearing loss with more than 30 dB air-bone gap and concomitant tinnitus will undergo Stapedotomy surgery to resolve the ossicular chain stiffness following otosclerosis. The surgery would be done under general anesthesia or sedation through an intracanal incision. A hole would be drilled in the stapedius footplate and a Teflon piston prosthesis would be inserted in place.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Mehrdad Jafari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akhondzadeh

Street address

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Email

research@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

1

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

Mehrdad Jafari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Title and more details about the data/document

All data can be published after deleting the recognition data.

When the data will become available and for how

long

from 2020

To whom data/document is available

researchers of academic institutes

Under which criteria data/document could be used

To be used in meta-analysis

From where data/document is obtainable

Otorhinolaryngology research center of Tehran university
of medical sciences

**What processes are involved for a request to access
data/document**

An email must be sent to the research corresponding
author.

Comments