

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of Stapedotomy surgery on tinnitus in Otosclerosis patients

Protocol summary

Study aim

To find the effect of Stapedotomy surgery to improve Tinnitus in Otosclerosis patients.

Design

A prospective trial will be conducted on Otosclerosis patients at Loghman Hakim hospital in Isfahan, Iran, from 2021 to 2022.

Settings and conduct

This study will be performed in Loghman Hakim hospital in Isfahan, Iran. To compare tinnitus pitch, otosclerosis patients will be divided into A) high pitch tinnitus frequency (2 kHz and more), B) medium pitch tinnitus frequency (500 – 2000 Hz), and C) low pitch tinnitus frequency (≤ 500 Hz). Informed consent will be obtained from each participant. All surgeries will be performed by one surgeon with the same methods. The audiometry will be performed for all groups at baseline, one and six months after stapedotomy.

Participants/Inclusion and exclusion criteria

All patients referred to Loghman Hakim hospital for stapedotomy surgery in 2021-2022 will be included and those who may get harmed or disadvantaged by the intervention will be excluded.

Intervention groups

Patients with high pitch tinnitus (2 kHz and more), B) patients with medium pitch frequency (500 – 2000 Hz), and C) patients with low pitch frequency (≤ 500 Hz).

Main outcome variables

tinnitus frequency changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191114045437N1**

Registration date: **2022-06-01, 1401/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-01, 1401/03/11**

Update count: **0**

Registration date

2022-06-01, 1401/03/11

Registrant information

Name

Niloufar Iraj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 7673

Email address

niloufar.iraji@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-23, 1400/10/02

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Stapedotomy surgery on tinnitus in Otosclerosis patients

Public title

Effect of Stapedotomy on tinnitus

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Otosclerosis patients who refer to Loghman Hakim

Hospital, Isfahan, Iran for stapedotomy surgery
Exclusion criteria:
Acoustic trauma Blood biochemistry abnormalities, including anemia, vitamin B12 deficiency, thyroid function test abnormalities Previous ear surgery history
Decline to participate in study

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

national research ethics committee

Street address

loghman hakim hospital

City

tehran

Province

Tehran

Postal code

1333625445

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.SBMU.MSP.REC.1398.064

Health conditions studied

1

Description of health condition studied

otosclerosis

ICD-10 code

H80

ICD-10 code description

Otosclerosis

Primary outcomes

1

Description

tinnitus frequency and loudness changes in patients with stapes surgery

Timepoint

before , one month, six months after surgery

Method of measurement

Audiometry

Secondary outcomes

empty

Intervention groups

1

Description

Patients with Otosclerosis who will undergo stapedotomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

loghman Hakim hospital

Full name of responsible person

Niloufar Iraji

Street address

Makhsus st. Hor squ.

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Postal code

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Phone

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Web page address

<http://lhmc.sbm.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloufar Iraji

Street address

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Web page address

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

10

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloufar iraji

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
for patients privacy

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
we publish all information with detail in article

When the data will become available and for how long
now we can present information

To whom data/document is available
all people

Under which criteria data/document could be used
for increase researcher's data

From where data/document is obtainable
Loghman Hakim Hospital records

What processes are involved for a request to access data/document
net search or go to hospital records ward

Comments