

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

13333625445

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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niloufar.iraji@yahoo.com

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

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Web page address
 https://sbmu.ac.ir
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
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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