

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Changes in the air Conduction due to replacement of footplate of stapes bone with fat in patients with radical mastoidectomy

Protocol summary

Study aim

Determining the hearing changes of patients with a history of radical mastoidectomy who undergo surgery to replace the stapes bone plate with fat.

Design

Clinical trial with a single intervention group, non-randomized, phase 2 on 35 patients.

Settings and conduct

Patients who have a previous history of mastoidectomy and have referred to the ENT clinic of Loqman Hospital in Tehran are evaluated by audiometry test. Then, if all the inclusion criteria are met, the epithelium and foot plate of healthy stapes bone will be removed in the area of the oval valve, and the valve will be covered with a fat graft removed from the lobule, and Gelfoam will be placed on it. One day after the surgery, diapason tests will be done to make sure of the carrier. Then, the patient is subjected to an audiometry test at intervals of one month and six months after the surgery, and the hearing changes are compared with before the surgery.

Participants/Inclusion and exclusion criteria

Patients older than 18 years old and with a history of previous radical mastoidectomy who have at least 6 months of dry cavity, and in the audiometric test, bone conduction is less than 35, air conduction is more than 50, the affected ear be non-serviceable and the opposite ear be serviceable, enrolled in the study. Patients with evidence of active ear infection are not included in the study.

Intervention groups

The healthy stapes bone epithelium and footplate in the oval valve area will be removed and the valve will be covered with a fat graft removed from the lobule.

Main outcome variables

Hearing changes based on standard audiometric test parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055606N2**

Registration date: **2022-10-15, 1401/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-15, 1401/07/23**

Update count: **0**

Registration date

2022-10-15, 1401/07/23

Registrant information

Name

alireza moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6522 4135

Email address

alirezamoradi_md@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Changes in the air Conduction due to replacement of footplate of stapes bone with fat in patients with radical mastoidectomy

Public title

Changes in the air Conduction due to replacement of footplate of stapes bone with fat

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18 years History of radical mastoidectomy Had a dry cavity for at least 6 months The amount of air conduction is more than 50 The amount of bone conduction is less than 35 The affected ear is non-serviceable The opposite ear is serviceable

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

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

Ethics Committee of Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Tehran

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1333635445

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.SBMU.MSP.REC.1400.159

Health conditions studied

1

Description of health condition studied

radical mastoidectomy

ICD-10 code

H95.1

ICD-10 code description

Other disorders of ear and mastoid process following mastoidectomy

Primary outcomes

1

Description

Audiometric parameters

Timepoint

Before, one month and six months after the operation

Method of measurement

Standard audiometric test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Epithelium and foot plate of the healthy stapes bone in the area of the oval valve will be removed and the valve will be covered with fat taken from the lobule and gelfoam will be placed on it.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Educational Hospital

Full name of responsible person

Dr. Farhad Mokhtari Nejad

Street address

Loqman Hakim Hospital, Kamali Street, Lashgar Crossroads

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Postal code

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Phone

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Email

loghman.hospital@sbmu.ac.ir

Web page address

https://lhmc.sbmu.ac.ir/index.jsp?pageid=18901&p=1

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St,
Yemen St, Shahid Chamran Highway, Velenjak

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1985717434

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zarghi@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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Moradi

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

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Asistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Moradi

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

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Fax

Email

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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

Yes - There is 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

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

The clinical report and study protocol will be published in the form of a scientific article. However, no decision has been made yet regarding the publication of the data file of the participants and the analysis map. However, it can only be provided to related individuals or organizations in special cases

When the data will become available and for how long

The access period starts from 2022

To whom data/document is available

Academic researchers and healthcare officials

Under which criteria data/document could be used

The IPD file and the study protocol can be used upon request by relevant organizations and decision-makers in the field of health in order to check its accuracy and/or to use it in the design of subsequent studies by mentioning the primary source.

From where data/document is obtainable

Ear Research Center of Luqman Hakim Hospital

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

Written request to the scientific officer of the study

Comments