Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of application of dexamethasone in the middle ear during stapedotomy on hearing results of patients with otosclerosis

Protocol summary

Study aim
Determining the effect of dexamethasone use in the middle ear during stapedotomy surgery on the hearing results of patients with otosclerosis

Design
Non-probabilistic and available methods will be used for sampling and random blocking method will be used to assign individuals in the intervention and control groups. In this way, the blocks will be arranged using a table of random numbers, and a code will be assigned to each client and candidate for action, based on which the code will determine whether the person is in the intervention or control group.

Settings and conduct
In the control group, routine stapedotomy will be performed, and in the intervention group, immediately after perforation of the footplate by the perforator, 0.3 cc of dexamethasone will be placed in the middle ear and on the oval window, and a Teflon piston or titanium prosthesis will be placed inside the oval window. Double-blind (researcher and patient)

Participants/Inclusion and exclusion criteria
all patients with otosclerosis who have conductive hearing impairment of more than 30 decibels in the recent audiometry in the affected ear. Patients who have a history of previous stapedotomy surgery or a history of other ear diseases, such as meningitis or upper semicircular canal dehiscence, will be excluded if they do not return within the specified time after surgery.

Intervention groups
In the control group, routine stapedotomy will be performed, and in the intervention group, immediately after perforation of the footplate by the perforator, 0.3 cc of dexamethasone will be placed in the middle ear and on the oval window, and a Teflon piston or titanium prosthesis will be placed inside the oval window.

Main outcome variables
Before and 6 months after high frequency full frequency audiometry

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220111053690N1**
Registration date: **2022-05-01, 1401/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**
Update count: **0**

Registration date
2022-05-01, 1401/02/11

Registrant information

Name
Sepideh Zoafa

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6672 7061

Email address
sepidehzoafa@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of application of dexamethasone in the middle ear during stapedotomy on hearing results of patients with otosclerosis

Public title
The effect of application of dexamethasone in the middle ear during surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with otosclerosis whose conductive hearing impairment exceeds 30 dB on recent audiometry in the affected ear
Exclusion criteria:
Patients who have a history of previous stapedotomy surgery a history of other ear diseases, such as meningitis or upper semicircular canal dehiscence will be excluded if they do not return within the specified time after surgery.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is block. Four blocks are defined from intervention group (A) and control (B). (AABB, ABAB, ABBA, BABA, BAAB) It is written on cards 1 to 6 and the cards are placed in the envelope. The cards are then randomly selected and a random string is made from the sequence of selected cards. Patients in the intervention and control groups are included in the study based on this sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
. The study is single blind. The surgeon and researcher are aware of the groups but the patient and the data monitoring committee are kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Amir A'lam Hospital Complex
Street address
Amir A'lam hospital, North Sa'di Ave , Darvaze Dolat
City
tehran
Province
Tehran
Postal code
114576511
Approval date
2022-03-19, 1400/12/28
Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1401.001

Health conditions studied

1

Description of health condition studied
otosclerosis
ICD-10 code
H80
ICD-10 code description
Otosclerosis

Primary outcomes

1

Description
Hearing improvement after dexamethasone use during middle ear surgery in otosclerosis in patients with a gap of 30 dB
Timepoint
Before and 6 months after complete high frequency audiometric stapedotomy at the audiometry center
Method of measurement
Audiometry and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the control group, routine stapedotomy will be performed, and in the intervention group, immediately after perforation of the footplate by the perforator, 0.3 cc of dexamethasone will be placed in the middle ear and on the oval window, and a Teflon piston or titanium prosthesis will be placed inside the oval window. Will be placed. The area around the prosthesis in the oval window will be covered with fat removed from the lobule, and without placing the foam

gel in the middle ear, the flap will be returned and the canal foam gel will be embedded.

Category

Treatment - Surgery

2

Description

Control group: routine stapedotomy will be performed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini and Amir Alam hospitals

Full name of responsible person

Behrooz Amirzargar

Street address

Amir A'lam Hospital, North S'adi Ave, Darvaze dolat

City

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114576511

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+98 21 6672 7061

Email

sepidehzoafa@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotoohi

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

City

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Province

Tehran

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1145765111

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

https://vcr.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

100

Public or private sector

Private

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

Tehran University of Medical Sciences

Full name of responsible person

Behrooz Amirzargar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Behrooz Amirzargar

Position

Associate professor

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Person responsible for updating data

Contact
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Full name of responsible person
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Position
Otorhinolaryngology resident
Latest degree
Medical doctor
Other areas of specialty/work
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Fax
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Sepidehzoafa@gmail.com

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
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
Yes - There is a plan to make this available
Analytic Code
No - There is not 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 is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions will be available
Under which criteria data/document could be used
Random blocking method will be used to assign individuals in the intervention and control groups. In this way, the blocks will be arranged using a table of random numbers, and a code will be assigned to each client and candidate for action, based on which the code will determine whether the person is in the intervention or control group.
From where data/document is obtainable
sepideh zoafa - otorhinolaryngology resident- Amir Alam Hospital- 00989300596664
What processes are involved for a request to access data/document
After sending the request and the availability of data in Evin, the opportunity will be available
Comments