Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of adding corticosteroids in the middle ear before Embedding implant in surgery of otosclerosis patients on reducing postoperative vertigo

Protocol summary

Study aim
Evaluation of the effect of adding corticosteroids in the middle ear before embedding implant in surgery of otosclerosis patients on reducing postoperative vertigo

Design
Clinical trial with control group, parallel, double blinded, randomized, 3rd phase on 35 patients, random blocks were used for randomization.

Settings and conduct
This clinical trial between 2022-2024 occur on the patient with hearing reduction and have positive history of otosclerosis in family evaluations and have hearing loss 2k in audiogram and have high risk of otosclerosis and surgery indication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis otosclerosis based on audiometry; familial history; air bone gap 20 decibel in 0.5, 1, 2, 3 kilohertz without any anomaly and timpano membrane perforation; age over 18 years old; have indication for surgery. Exclusion criteria: sensitivity to corticosteroids; patients with asthma; patients with hypertension; no referral for primary and secondary evaluations; history of middle ear surgery.

Intervention groups
Patients who undergone stapedectomy before insertion of implant 4 drops of dexamethasone use on stapes osteon and oval window and in the control group normal saline use instead of corticosteroid at the same place and then implant insert

Main outcome variables
Hospital stay; hearing reducing; vertigo severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221114056502N1**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Arvin shahzamani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 323 5343

Email address
arvin.shahzamani@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of adding corticosteroids in the middle ear before Embedding implant in surgery of otosclerosis patients on reducing postoperative vertigo

Public title
Evaluation of the effect of adding corticosteroids in the middle ear before Embedding implant in surgery of otosclerosis patients on reducing postoperative vertigo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of otosclerosis based on audiometry, familial history, air-bone gap more than 20 decibel in 0.5, 1, 2, 3 kilohertz, absens of anomaly and timpano membrane perforation Age older than 18 y/o Have surgery indications
Exclusion criteria:
Sensitivity to corticosteroids Patients with asthma Patients with hypertension No referrals patients for primary and secondary evaluations History of middle ear surgery
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selection process and pre- and post-operative assessments. The block size will be equal and is set to 4, the sufficient and estimated sample size will be 35, then the allocation code is set to sequential. The analytics will use the output of software to determine the sequence and allocation of patients. Then each code is written on a non-transparent envelope and a paper is put in it in which the intervention or control is written on the paper. The series of the envelope will be according to the software's list and they will keep in a large box with a locker. The analytics has the key for the box and this box will be kept in his room which the analytics has its only key and has no windows. As the patients enrolled in the study sequentially, the analytics use the designated envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both patients and clinicians are blinded in this study. drug and placebo use in the similar pack with label of A or B. At the beginning of procedure, the clinicians write the label of drug and the top of the questioner.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
ENT academia-Taleghany hospital-Tehran_Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-10-18, 1401/07/26
Ethics committee reference number
IR.SBMU.MSP.REC.1401.358

Health conditions studied

1

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

Primary outcomes

1

Description
Reducing vertigo after surgery
Timepoint
At time of discharge - 4 week after operation
Method of measurement
Vertigo disability questionnaire - Audiometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in the intervention group patients

undergo stapedectomy surgery before implanting the prosthesis 4 drops of dexamethasone are poured into the base of the steps bone and the oval window.

Category

Treatment - Drugs

2

Description

Control group: in the control group instead of dexamethasone a few drops of normal saline are poured into the base of the steps bone and the oval window and then the prosthesis is going to get inserted.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Behrouz Barati

Street address

ENT department- Taleghani hospital- A'rabi street, Yaman street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 913 323 5343

Fax

Email

arvin.shahzamani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

Street address

ENT department- Taleghani hospital- Tehran - iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 913 323 5343

Email

aliziai@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

Behrouz Barati

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

ENT department- Taleghani hospital- A'rabi street, Yaman street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 913 323 5343

Email

b_barati@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Position

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Postal code
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Phone
+98 913 323 5343
Email
b_barati@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arvin Shahzamani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
ENT department- Taleghani hospital- A'rabi street, Yaman street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 913 323 5343
Fax
Email
arvin.shahzamani@yahoo.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
Undecided - It is not yet known if there will be 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