

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

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Tehran

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**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

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**Province**

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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

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**Person responsible for scientific 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**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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Yaman street, Tehran, Iran**City**

Tehran

**Province**

Tehran

**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