

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison of effects of intratympanic Dexamethasone and intratympanic Betamethasone LA therapy for patients with Idiopathic Sudden Sensorineural Hearing Loss: A randomized clinical trial study

Protocol summary

Summary

The purpose of this study is to compare of the effectiveness of Dexamethasone and long-acting Betamethasone intratympanic injection of intratympanic in treatment of Sudden Sensorineural Hearing Loss (SSNHL). This study is in the form of a randomized clinical, that the patients are divided into two groups of 47 people through the random blocking method. The patients of 18-70 years old who suffered from SSNHL and did not respond to the systemic treatment by oral prednisolone for 10 days, are randomly and single-blindly included in an intratympanic treatment groups based on certain criteria (a reduction of at least 30 dB in the hearing frequency in relation to 3 consecutive frequencies in a period of 3 days). It should be highlighted that the included patients must not state any history of ear disease. The following patients are excluded from this study: those with some pathological problems in the middle ear, those with experience of the intratympanic injection for similar disease, those with bilateral SSNHL. The selective patients in their respective groups are given 2 intratympanic injections a week (twice a week); totally, 6 injections are given within 3 weeks. At the end of the 6th injection, the patients will undergo audiometry again, and the results will be compared with those of the first audiometry (before the intratympanic treatment starts); afterwards, the results are analyzed and recorded. After receiving treatment, the patients will be followed up by audiometry and evaluated in the intervals of 1 month, 2 month, and 6 months. At the end of the first month, and upon the termination of the treatment, the patient will undergo MRI and other required tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012832069N2**

Registration date: **2017-08-17, 1396/05/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name

Ardavan Tajdini

Name of organization / entity

Tehran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-05-04, 1396/02/14

Expected recruitment end date

2018-05-03, 1397/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of effects of intratympanic Dexamethasone and intratympanic Betamethasone LA therapy for patients with Idiopathic Sudden Sensorineural Hearing Loss: A randomized clinical trial study	
Public title	Betamethasone LA effects versus Dexamethasone in treatment of Sudden Sensory Hearing Loss
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: age between 18-70 years old; patient with SSHL and history of systemic corticosteroids treatment without response to it; whitout history of ear disease; SSHL without certain causes. Exclusion criteria: pathology in the middle ear (tympanic membrane perforation, surgery on the ear) bilateral SSHL; previous intratympanic injection for the same disease
Age	From 18 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 94
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Single blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Vice chancellor for research, Tehran University of Medical Sciences
Street address	Central Department Of University, 6th floor, Keshavarz blv, Qods st-
City	Tehran
Postal code	
Approval date	2017-05-03, 1396/02/13
Ethics committee reference number	IR.TUMS.VCR.REC.1396.2201

Health conditions studied	
<u>1</u>	
Description of health condition studied	sudden sensorineural hearing loss
ICD-10 code	H91.2
ICD-10 code description	Sudden idiopathic hearing loss
Primary outcomes	
<u>1</u>	
Description	Hearing cutoff
Timepoint	Before intervation, after intervation at force,1month after intervation,2months after the end of the intervation,6months after the end of the intervation
Method of measurement	PTA
Secondary outcomes	
<u>1</u>	
Description	Vertigo
Timepoint	After the end of the intervation at force,1month and 2months and 6months after the end of the intervation
Method of measurement	Questionary
Intervention groups	
<u>1</u>	
Description	Intervation group: Using LA Betamethasone 0.4-0.6 cc for Intratympanic injection that performed 6 injections twice aweek.
Category	Treatment - Drugs
<u>2</u>	
Description	Control group : Using Dexamethasone 0.4-0.6 cc for Intratympanic injection that performed 6 injections twice aweek.
Category	Treatment - Drugs
Recruitment centers	
<u>1</u>	
Recruitment center	

Name of recruitment center

Amir Alam hospital

Full name of responsible person

Doctor Ardavan Tajdini

Street addressAmir Alam hospital, The North of Saadi street,
Darvaze Dolat, Enqelab blv, Tehran.**City**

Tehran

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Dr Ardavan Tajdini

Position

ENT professor

Other areas of specialty/work**Street address**

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ardavan-taj@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Tehran University of
Medical Sciences**Full name of responsible person**

Doctor Masoud Yousefian

Street addressCentral Department of University, 6th floor, Qods st,
Keshavarz blv**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Tehran University of Medical
Sciences**Proportion provided by this source**

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Doctor Shima Hajibegloo

Position

ENT Resident

Other areas of specialty/work**Street address**Amir Alam Hospital, Darvaze Dolat, Saadi st, Enqelab
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Postal code**Phone****Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Dr Shima Hajibegloo

Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty