Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Effect of Intratympanic injection of dexamethasone via catheter in Sudden Sensory Neural Hearing Loss (SSNHL)

Protocol summary

Study aim

Comparing the results of hearing improvement with two methods of routine injection and injection with catheter in the middle ear in patients with severe sudden sensorineural hearing loss.

Design

The research is a prospective clinical trial. Two treatment groups with random selection of patients in each group, A double-blind study, each group 30 patients, a total of 60 patients, randomization with Random Allocation software.

Settings and conduct

All patients of severe SSNH will Including in the study at Kashani and Al-Zahra Hospital in Isfahan. Blinding will be done at the level of data collection and statistical analysis. Classic Intratympanic injection for one group and injection via gray catheter for another group will done

Participants/Inclusion and exclusion criteria

Including criteria: Adults (18 to 75 years old) Severe sensorineural hearing loss (SRT equal to or higher than 60 dB) Less than two weeks from the onset of the disease Excluding criteria: Lack of consent for treatment at any stage Presence of active Otologic infection More than a month after the onset of the disease Presence of other causes of hearing loss (tumor, toxic drugs, Acoustic trauma, ear surgery)

Intervention groups

In the catheter injection treatment group, dexamethasone injection treatment is performed by inserting a catheter in the ear for two weeks. In the classical intratympanic injection treatment group, six dexamethasone injections are performed every other day

Main outcome variables

Hearing threshold pure tone (PTA), speech reception threshold (SRT)

General information

Reason for update

Acronym

SSNHL

IRCT registration information

IRCT registration number: **IRCT20211125053181N2**
Registration date: **2023-11-11, 1402/08/20**
Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**
Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Sohrab Rabiei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-05, 1402/09/14

Expected recruitment end date

2024-07-04, 1403/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Intratympanic injection of dexamethasone via catheter in Sudden Sensory Neural Hearing Loss (SSNHL)

Public title
Effect of Intratympanic injection of dexamethasone via catheter in Sudden Sensory Neural Hearing Loss

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult age (18-75 age old) Hearing loss greater than 60db based on SRT In the first two weeks of the disease

Exclusion criteria:
Lack of consent for treatment at any stage Presence of active infectious ear disease Referral more than a month after the onset of the disease Presence of other causes of hearing loss (ear tumor, toxic drugs, sound trauma, ear surgery)

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation method is used In this way, the total size of the sample is determined and the set of group A and group B is randomly defined. Patients are entered randomly in the group by lottery. Random allocation software is used to speed up the work

Blinding (investigator's opinion)
Double blinded

Blinding description
The treatment methods are explained to the patient and the patient is aware of his treatment group, so there is no possibility of blinding the study for the patient. For this reason, blinding is done only for the outcome evaluator and data analyst. The data are in the form of audiometry results, so the outcome evaluator and the analyst are not in contact with the patient and do not know the patient's treatment group.

Placebo
Not used

Assignment
Parallel

Other design features
For treat sudden-onset sensorineural hearing loss by using a catheter, previous researchers had used very invasive methods, which was to create a subcutaneous tunnel in the ear canal and pass the catheter through the Middle ear, which is an invasive method. In our method, as simple as VT surgery, first myringotomy is performed and by measuring the appropriate length of the catheter, the end of the catheter is inserted into the middle ear, and the end of the catheter that exits the ear canal is stitched to the skin at several points, which minimized catheter mobility and therefore this method is less invasive in the ear canal and can be performed technically by any otolaryngologist.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address
No. 110, Nik Nafs Alley, Vahid St., Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8175817393

Approval date
2023-05-24, 1402/03/03

Ethics committee reference number
IR.MUI.MED.REC.1402.223

Health conditions studied

1

Description of health condition studied
Sudden Sensory-Neural Hearing Loss (SSNHL)

ICD-10 code
H91.20

ICD-10 code description
Sudden idiopathic hearing loss, unspecified ear

Primary outcomes

1

Description
Hearing threshold pure tone (PTA) and speech reception threshold (SRT) in the initial audiometry and then their changes in the follow-up period.

Timepoint
At the beginning of the study and 14, 30, 90 days after the start of treatment

Method of measurement
Pure tone audiometry (PTA) and assessment of changes in speech perception threshold (SRT) before and after treatment.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with severe sudden hearing loss in the catheter injection group. In these patients, under local anesthesia of the ear canal, a tympanotomy will perform in the posterior inferior of the tympanic membrane and the catheter will be measure and the end of the catheter will place in the myringotomy site as in the VT operation, and the outer end of the catheter will be sutured to the upper part of the auricle at the level of helix junction and the rest of catheter is fixed behind the patient's ear. A gray feeding tube catheter will be used for patients. During two weeks, the patient will undergo two injection per day, and inject two milligrams of dexamethasone slowly with a needle-free insulin syringe at the catheter, and the infusion will be done by a assistant who collaborates with the study. The patients will followed up for three months and immediately after the completion of the treatment, two weeks later, one month later and three months later, hearing evaluation is done for the patients and the results are recorded.

Category
Treatment - Drugs

2

Description
Control group: For patients with severe Sudden Sensorineural hearing loss who are in the classic ear injection group, dexamethasone injection will be performed every other day using spinal needle number 25. At least four injections are given to the patient during an eight-day period.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital, Isfahan
Full name of responsible person
Mohammad Shahab Akhwan
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Sohrab Rabiei

Position
Associate Professor of Otology & Neurotology

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Ayatollah Kashani Street, Office of Ear Throat Nose and Head and Neck Surgery

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Full name of responsible person
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Position
Associate Professor of Otology & Neurotology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is 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
Start the access period immediately after printing the results

To whom data/document is available
For researchers working in academic and scientific institutions and researchers in industrial centers

Under which criteria data/document could be used
Analysis with reference to the data source is allowed

From where data/document is obtainable
Dr. Mohammad Shahab Akhavan
dr.m.shahab.akhavan@gmail.com 09103986427

What processes are involved for a request to access data/document
ontact the researcher and announce the email, receive the documents by email after a maximum of one week

Comments