

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of dexamethasone injection in the middle ear cavity for the treatment of sudden sensorineural hearing loss and comparison with standard methods

Protocol summary

Study aim

Evaluation of dexamethasone injection in the middle ear cavity for the treatment of sudden sensorineural hearing loss and comparison with standard methods

Design

Randomized clinical trial using closed-door envelope with control group, and parallel groups, double-blind, phase 3 on 120 patients

Settings and conduct

This double-blind clinical trial (participants in the study and analyzers have been blinded) is performed on 120 patients with sudden sensorineural deafness referred to Imam Reza Hospitals in Mashhad. Eligible patients are divided into control group and two intervention groups after obtaining consent. Injection of dexamethasone in the middle ear cavity in control group is performed according to the standard guideline three times every 4 days in a 12-day period and other two interventions groups give the same amount of injection but over a 10-day period, twice a day in the first intervention group and once a day in the second intervention group.

Participants/Inclusion and exclusion criteria

Patients with sudden sensorineural hearing loss that is 72 hours to less than 30 days after the onset of symptoms and who do not have a known genetic sensorineural hearing loss or anomaly of the inner ear and lack sensitivity to prescription drugs and evidence of acute or chronic otitis media

Intervention groups

In the control group, 40 patients with sudden sensorineural hearing loss, in addition to routine treatment, injected dexamethasone into the middle ear cavity three times every 4 days for a period of 12 days. In the other two intervention groups, the same amount was injected. But in a 10-day period that is done twice a day in the first intervention group and once a day in the second intervention group.

Main outcome variables

Average hearing threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052721N1**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Navid nourizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

nourizadehn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of dexamethasone injection in the middle ear cavity for the treatment of sudden sensorineural hearing loss and comparison with standard methods

Public title
The effect of dexamethasone on sudden sensorineural hearing loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with sudden sensorineural hearing loss lasting from 72 hours to less than 30 days after the onset of symptoms
 Conscious consent to participate in the study
Exclusion criteria:
 Consumption other medications in addition to prescribed medications
 Pregnancy Allergy to prescription drugs
 Known genetic neurosensory deafness or known anomaly of the inner ear
 Pregnancy Breastfeeding

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups

Blinding (investigator's opinion)
Double blinded

Blinding description
The subjects and those evaluating the outcome will be unaware of the intervention and control groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Mashhad University of Medical Science
Street address
 Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9117699199
Approval date
 2020-02-18, 1398/11/29
Ethics committee reference number
 IR.MUMS.MEDICAL.REC.1399.232

Health conditions studied

1

Description of health condition studied
 Sudden sensorineural hearing loss
ICD-10 code
 H90.4
ICD-10 code description
 Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side

Primary outcomes

1

Description
 Average hearing threshold
Timepoint
 Mean hearing threshold before study and 10 and 12 days after using dexamethasone
Method of measurement
 Audiometry

Secondary outcomes

empty

Intervention groups

1

Description
 First Intervention group: In this group, 40 patients with sudden sensorineural hearing loss (SSNHL) in addition to routine treatment, would take middle ear cavity injection of dexamethasone in the amount of 0.5 cc twice a day for 10 days
Category
 Treatment - Drugs

2

Description

Second Intervention group: In this group, 40 patients with sudden sensorineural hearing loss (SSNHL) in addition to routine treatment, injection of dexamethasone in the middle ear cavity amount of 0.5 cc once a day for 10 days

Category

Treatment - Drugs

3

Description

Control group: In this group, 40 patients with sudden sensorineural hearing loss (SSNHL) in addition to routine treatment, injection of dexamethasone in the middle ear cavity amount of 0.5 cc and three times every 4 days in a 12-day period is performed, which is the guideline standard method of the American Society of Otolaryngology

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Navid Nourizadeh

Street address

Imam Reza (AS) Hospital, Imam Reza (AS) Square, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

91379 13316

Phone

+98 51 3854 3031

Email

nourizadehn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Navid Nourizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Reza (AS) Hospital, Imam Reza (AS) Square, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

91379 13316

Phone

+98 51 3854 3031

Email

nourizadehn@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Navid Nourizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Reza (AS) Hospital, Imam Reza (AS) Square, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

91379 13316

Phone

+98 51 3854 3031

Email

nourizadehn@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Navid Nourizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Reza (AS) Hospital, Imam Reza (AS) Square, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

91379 13316

Phone

+98 51 3854 3031

Email

nourizadehn@mums.ac.ir

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available