

# 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

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## Person responsible for scientific inquiries

### Contact

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Mashhad University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**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