

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### A comparative study of the effect of systemic and intratympanic corticosteroid treatment in improving vestibular tests in patients with sudden sensorineural hearing loss SSNHL with vestibular disorders

#### Protocol summary

##### Study aim

Determining and comparing the effect of systemic and intratympanic corticosteroid treatment in improving balance tests in SSNHL patients with balance disorders

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 2 on 40 patients. A table of random numbers was used for randomization.

##### Settings and conduct

This clinical trial will be conducted in 1402 in Kashani hospital in Isfahan city. People will be randomly divided into two groups. Oral treatment with prednisolone is at a dose of 1 mg per kilogram of body weight per day and with a maximum of 60 mg, which is done for 7 days and then stopped. Intratympanic treatment is in the form of injecting one ampoule of methylprednisolone once every other day up to 3 times. The time to start the treatment immediately after the diagnosis of the disease is at most 72 hours after the sensation of sudden hearing loss.

Blinding was not done in this study.

##### Participants/Inclusion and exclusion criteria

This study is conducted on people with SSNHL who meet the inclusion criteria including unilateral symptoms and informed consent and do not have exclusion criteria such as underlying problems and bilateral symptoms.

##### Intervention groups

group under intratympanic treatment and group under systemic treatment. Oral treatment with prednisolone is at a dose of 1 mg per kilogram of body weight per day and with a maximum of 60 mg, which is done for 7 days and then stopped. Intratympanic treatment is in the form of injecting one ampoule of methylprednisolone once every other day up to 3 times. The time to start the treatment immediately after the diagnosis of the disease is at most 72 hours after the sensation of sudden hearing loss.

##### Main outcome variables

vestibular function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230721058871N1**

Registration date: **2023-07-27, 1402/05/05**

Registration timing: **prospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **0**

##### Registration date

2023-07-27, 1402/05/05

##### Registrant information

##### Name

rouhollah Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 938 512 2176

##### Email address

mohammadimuq@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

A comparative study of the effect of systemic and intratympanic corticosteroid treatment in improving vestibular tests in patients with sudden sensorineural hearing loss SSNHL with vestibular disorders

**Public title**

systemic and intratympanic corticosteroid treatment in sensorineural hearing loss

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

informed consent unilateral impaired vestibular tests

**Exclusion criteria:**

neurological conditions bilateral unable to perform tests

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was done with the help of a table of random numbers and in a simple way. In this way, according to the number of participants in the study, the researcher puts his finger on a table number and moves up and left and generates random numbers. Then, based on the sample size of the research, a number of envelopes with aluminum wrappers, preparation and each of the random sequences created are recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. If the number is odd, the person is placed in the first group, and if the number is even, the person is placed in the second group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jarib

**City**

isfahan

**Province**

Isfahan

**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Approval date**

2023-06-25, 1402/04/04

**Ethics committee reference number**

IR.MUI.MED.REC.1402.122

**Health conditions studied****1****Description of health condition studied**

sudden sensorineural hearing loss

**ICD-10 code**

H90.5

**ICD-10 code description**

Unspecified sensorineural hearing loss

**Primary outcomes****1****Description**

Vestibular function

**Timepoint**

Before treatment and 6 weeks later

**Method of measurement**

cervical vestibular evoked myogenic potential

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Systemic treatment. Oral treatment with prednisolone is at a dose of 1 mg per kilogram of body weight per day and with a maximum of 60 mg, which is done for 7 days and then stopped.

**Category**

Treatment - Drugs

## 2

### Description

Intervention group: Intertympanic group. Intratympanic treatment is in the form of injecting one ampoule of methylprednisolone once every other day up to 3 times.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashani hospital

##### Full name of responsible person

Rouhollah Mohammadi

##### Street address

kashani street, Kashani hospital

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

mohammadimuq@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Gholamreza Asgari

##### Street address

Hezar Jarib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

askari@mui.ac.ir

##### 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

Rouhollah Mohammadi

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Ear, Nose, and Throat

##### Street address

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Rouhollah Mohammadi

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resident

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##### Email

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

rouhallah mohammadi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Province**

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**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Phone**

0098316680048

**Email**

mohammadimuq@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

no more information

**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