

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

Rouhollah Mohammadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Latest degree

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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