

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The effectiveness of intratympanic injection of nanogel dexamethasone versus non-nanogel dexamethasone in treatment of patients with Sudden Sensorineural Hearing Loss (SSNHL), a double blind clinical trial

Protocol summary

Study aim

The aim is to evaluate the effect of intratympanic injection of dexamethasone in the form of nanogel in the treatment of patients with Sudden Sensorineural Hearing Loss.

Design

The clinical trial has a control group, with parallel, non-randomized, phase 3 groups on 90 patients, each group consisting of 45 patients.

Settings and conduct

Research location is Shafa clinical research base in Kerman. Study population: All patients who come to the ENT clinic of Shafa Hospital with the complaint of sudden sensorineural hearing loss. The study is double-blinded, both the researcher and the patient are blind. For double blinding, the nanogel form and the usual form of dexamethasone were prepared by a nanopharmacologist and presented to the researcher in containers of the same shape with a specific number that only the manufacturer had the information about it. And the patients in both groups received drugs with similar shape.

Participants/Inclusion and exclusion criteria

Inclusion condition: Sudden unilateral sensorineural hearing loss. Exclusion conditions: otitis media, history of ear surgery, Meniere's disease, acoustic trauma, barotrauma, evidence of retrocochlear disease, genetic hearing loss or known inner ear abnormality, diabetes, immune deficiency, heart disease and Sensorineural hearing loss with other known causes

Intervention groups

Intervention group: dexamethasone as 20-mg nanogel form will be injected in the tympanic membrane. 4 times during a period of 8 days, with one day in between. Also, for 14 days, they will receive oral prednisolone at the rate of 1mg/kg up to maximum of 60 mg/day. Control group: received doses of usual dexamethasone (4 mg) and they

will also receive oral prednisolone, similar to intervention group.

Main outcome variables

Hearing loss; vertigo; tinnitus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220307054210N1**

Registration date: **2023-04-05, 1402/01/16**

Registration timing: **retrospective**

Last update: **2023-04-05, 1402/01/16**

Update count: **0**

Registration date

2023-04-05, 1402/01/16

Registrant information

Name

Fereshteh Fazlinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3246 1031

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-26, 1401/01/06

Expected recruitment end date

2023-03-26, 1402/01/06

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of intratympanic injection of nanogel dexamethasone versus non-nanogel dexamethasone in treatment of patients with Sudden Sensorineural Hearing Loss (SSNHL), a double blind clinical trial

Public title
The efficacy of intratympanic injection of nanogel dexamethasone in Sudden Sensorineural Hearing Loss (SSNHL) treatment,

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
One-way SSNHL at 30 dB at three consecutive frequencies generated in 72 hours or less The time period from the time of hearing loss until the patient is admitted to the hospital for the procedure is less than or equal to 45 days
Exclusion criteria:
Evidence of otitis media on examination and history
Known history of ear anomalies
Evidence of retrocuclear disease, history of meniere's disease
history of acoustic trauma
history of immunodeficiency
history of sudden sensory neural hearing loss with other known causes
history of heart disease

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make blind the researcher and the interpreter, the concentrated form of dexamethasone (nanogel) and the usual form of dexamethasone were prepared by a nanopharmacologist and presented to the researcher in containers of the same shape with specific numbers. We did not have the power to distinguish the control group from intervention group. Only the manufacturer of the concentrated solution had the information about which drug each container number corresponded to. And the patients in both groups

received intratympanic injection treatment and oral medication, which were similar, and the patient did not know whether he was in the control or intervention group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-
Kerman University of Medical Sciences

Street address

Imam Khomeini Highway, next to Shahid Bahonar
University, Afzalipur Medical Education Center

City

kerman

Province

Kerman

Postal code

7616913355

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.KMU.AH.REC.1401.158

Health conditions studied

1

Description of health condition studied

Sudden Sensorineural Hearing Loss

ICD-10 code

H91.20

ICD-10 code description

Sudden idiopathic hearing loss, unspecified ear

Primary outcomes

1

Description

Hearing level

Timepoint

Measurement of the patient's hearing level at the beginning of the study (before the intervention) and 2 weeks after and 2 months after the start of the treatment period.

Method of measurement

The hearing level was measured with audiometric criteria (PTA and srt) using an audiogram.

2

Description

vertigo

Timepoint

Vertigo was examined before the start of treatment and 2 weeks and 2 months after the start of treatment

Method of measurement

Dizziness was investigated using a questionnaire

3

Description

tinnitus

Timepoint

tinnitus was examined before the start of treatment and 2 weeks and 2 months after the start of treatment

Method of measurement

tinnitus was investigated using a questionnaire

Secondary outcomes

1

Description

SRT :(speech recognition threshold)

Timepoint

before intervention and 2 and 4 weeks after intervention

Method of measurement

audiometry

2

Description

PTA:(pure tone audiometry)

Timepoint

before intervention and 2 and 4 weeks after intervention

Method of measurement

audiometry

Intervention groups

1

Description

Control group: Patients in this group will receive oral prednisolone at a dose of 1 mg per kg to a maximum of 60 mg daily for 14 days.

Category

Treatment - Drugs

2

Description

Intervention group: for patients of this group, 4 doses of 20 mg nano-gel form of dexamethasone ampule will be injected into the posterior-inferior quadrant of the tympanic membrane by the pink angiocatheter (20 G) with the patient's head rotated 45 degrees to the other side. The injection will be performed under a microscope, and the success of the injection will depend on the observation of the tympanic membrane protruding from the fluid injected into the middle ear; If unsuccessful, re-

injection will be given with less dexamethasone. This operation will be performed 4 times during an 8-day period every other day. Each patient will also receive oral prednisolone at a dose of 1 mg per kg for a maximum of 60 mg daily for 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Maryam Amizadeh

Street address

Shafa Hospital, Kowsar Blvd, Kerman, Iran

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+98 34 3211 5780

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fereshteh Fazlinezhad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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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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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

Data can be shared after deidentifying people. The specific titles of the documents include the demographic characteristics of the people participating in the study and the data obtained from the audiometry of the patients including pta and srt before and after the intervention and qualitative data such as dizziness and tinnitus and can be shared. .

When the data will become available and for how long

Access to data is possible 6 months after publishing the results.

To whom data/document is available

The data of this study will be available only to professionals working in academic and scientific

institutions.

Under which criteria data/document could be used

I do not have special conditions for access and use of data by others.

From where data/document is obtainable

Data applicants can access the data by sending a request through my email or mobile phone.

fereshtehfa@ymail.com 09158671902

What processes are involved for a request to access data/document

It does not go through a special process and the data will be sent to them as soon as the request is received.

Comments