Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 retrocuclear 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, for14 days, they will receive oral prednisolone at the rate of1mg/kg up to maximum of 60 mg/day.Control group: recieved 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)

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+98 56 3246 1031

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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 anomaleis 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 couses 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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۷۶۱۸۷۵۱۱۵۱
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Email
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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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7616913555
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Fax
+98 34 3132 5830
Email
m.amizadeh@kmu.ac.ir
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

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Fereshteh Fazlinezhad

Position
Resident

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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