

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the therapeutic effects of intratympanic injections of Triamcinolon and Dexametason who suffer from sudden sensorineural hearing loss

Protocol summary

Study aim

Determining and comparing the therapeutic effect of intratympanic injection of triamcinolone and dexamethasone in patients with sudden sensorineural hearing loss

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 3 on 62 patients. Blocks of four are used for randomization.

Settings and conduct

The statistical population includes patients referred to Imam Khomeini Hospital who suffer from sudden sensorineural hearing loss with hearing loss of more than 30 dB in three consecutive frequencies in less than three days in audiometry, which are randomly divided into intervention and control group. Intratympanic injection of triamcinolone will be given to the intervention group and intratympanic injection of dexamethasone will be given to the control group. The study was double-blind and participants and the audiologist evaluating the audiometry were kept blind from being assigned to the study groups

Participants/Inclusion and exclusion criteria

Patients will be included in the study who have contraindications to receiving systemic corticosteroids such as uncontrolled diabetes, hematologic malignancies, etc.

Intervention groups

The intervention group will be injected with intratympanic triamcinolone ampule and the control group will be injected with intratympanic dexamethasone ampule.

Main outcome variables

Hearing improvement based on audiometry .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171004036554N4**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Hamed Emami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of intratympanic injections of Triamcinolon and Dexametason who suffer from sudden sensorineural hearing loss

Public title

Comparison of the therapeutic effects of intratympanic injections of Triamcinolon and Dexametason who suffer from sudden sensorineural hearing loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with SSNH diagnosis who are candidates for intratympanic injection Patients who have a contraindication to receive systemic corticosteroids, such as underlying diseases like diabetes or defective immune disorders . Patients who are interested in receiving intratympanic corticosteroids instead of systemic corticosteroids .

Exclusion criteria:

Patients who are candidates for receive systemic corticosteroids Patients who are not volunteer to receive intratympanic corticosteroids

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Randomized

Randomization description

we use block randomization. we have blocks of four intervention (A) and four of control (B) groups and write them from 1-6 on cards and put them in a pocket, then choose them by chance and make a sequence of cards. We import patients of interventional or control group of our study from these sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient's consent states that the injection is done randomly with one of these drugs and the patient is unaware of the contents of the drug syringe. Also, the person who evaluates the patients' audiometry after the injection is unaware of which group the patient belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Amiralam Hospital

Street address

Saadi Avenue, Enghelab Street

City

Tehran

Province

Tehran

Postal code

1981613875

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1400.048

Health conditions studied

1

Description of health condition studied

Sudden sensorineural hearing loss

ICD-10 code

H91.23

ICD-10 code description

Sudden idiopathic hearing loss, bilateral

Primary outcomes

1

Description

Hearing improvement based on audiometry

Timepoint

Complete response to treatment refers to an increase of 30 dB after 15 to 45 days after IT injection of dexamethasone and triamcinolone. The relative response to treatment refers to an increase of 10 dB 15 to 45 days after IT injection of dexamethasone. An improvement of less than 10 decibels will be considered as no response or failure of treatment

Method of measurement

Based on audiometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, using

Triamcinolone ampoule 0.4-0.6 cc for Intratympanic injection that performed 6 injections twice a week.

Category

Treatment - Drugs

2

Description

Control group: In the intervention group, using Dexamethasone 0.4-0.6 cc for Intratympanic injection that performed 6 injections twice a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Otorhynolaryngology clinic of Imam Khomeini hospital complex

Full name of responsible person

Hamed Emami

Street address

Imam Khomeini hospital complex , Bagherkhan Ave, South Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Qods Ave, Keshavarz Blv,

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Saleh Habibi

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamed Emami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Street address

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City

Tehran

Province

Tehran

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available