

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparing the therapeutic effects of oral corticosteroid, intratympanic corticosteroid and combined approach in patients with sudden sensorineural hearing loss

Protocol summary

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Summary

Sudden Sensorineural Hearing Loss (SSNHL) is an emergency issue in the field of ENT. The present study was designed to compare the therapeutic effects of 3 modalities among 150 subjects: group1) receiving oral prednisolone for 10 days (75mg). They will also be administered 0.6ml of placebo at days 1,5,9, and 13 intratympanically. group2) receiving 0.6ml of methyl prednisolone intratympanically at days 1,5,9, and 13 as well placebo orally. group3) receiving prednisolone as group 1 and methyl prednisolone as group 2 protocol. Meanwhile, serum level of TG, cholesterol, FBS, HBA1C, LDL, HDL, ESR, RF, ANA, and FTA-ABS will be assessed.

Recruitment status

Recruitment complete

Funding source

ENT research center, Tehran University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the therapeutic effects of oral corticosteroid, intratympanic corticosteroid and combined approach in patients with sudden sensorineural hearing loss

Public title

Treating sudden sensorineural hearing loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with SSNHL referring to Amiralam hospital within the first 10 day of onset
Exclusion criteria: receiving therapy in other centers; contraindication to corticosteroid such as pregnancy, diabetes mellitus, etc; previous history of SSNHL; immunocompromised subjects; fluctuating SNHL; previous history of hydropsis; history of brain pathology or temporal bone pathology; concurrent acute or chronic otitis; VDRL-positive cases; uncooperative subjects; referring after 10 days.

Age

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202159039N1**

Registration date: **2012-03-12, 1390/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

Name

Shahin Bastaninezhad

Name of organization / entity

Dep. ENT, AmirAlam Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6676 0269

Email address

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

None

Secondary trial Id

None

Registration date

empty

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

Tehran University of Medical Sciences, Ethics Committee

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2011-12-30, 1390/10/09

Ethics committee reference number

90-03-48-15295-42721

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

Idiopathic sudden sensorineural hearing loss

ICD-10 code

H91.2

ICD-10 code description

Sudden hearing loss NOS

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

Hearing loss

Timepoint

Before trial, one and 4 weeks following the intervention

Method of measurement

Audiometry

Secondary outcomes

empty

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

Group 1) Oral prednisolone (75mg) for 10 days, and 0.6ml of intratympanic placebo at days 1,5,9,13

Category

Treatment - Drugs

2**Description**

Group 2) 0.6ml intratympanic methyl prednisolone at days 1,5,9,13 and oral placebo for 10 days

Category

Treatment - Drugs

3**Description**

Group 3) oral prednisolone like group 1 and intratympanic methyl prednisolone like group 2

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralam Hospital

Full name of responsible person

Farzad Firouzi, MD

Street address

South Saadi, Amiralam Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

ENT Research center, Tehran University of Medical

Sciences

Full name of responsible person

Khorsandi Mohammadtaghi, MD

Street address

Amiralam Hospital

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

ENT Research center, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

ENT Reaserch center

Full name of responsible person

Farzad Firouzi, MD

Position

ENT Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty