Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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) receing prednisolone as group 1 and methyl prednisiolone as group 2 protocol. Meanwhile, serum level of TG, cholesterol, FBS, HBA1C, LDL, HDL, ESR, RF, ANA, and FTA-ABS will be assessed.

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

shahinbastani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

ENT research cneter, 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

Ttreating 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, diabetus 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; uncoopearte subjects; refering after 10 days.

Age

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

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Shahin Bastaninezhad, MD

Position
Assistant professor

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Person responsible for updating data

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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