

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of "intratympanic dexamethasone" with "Round Window Gelfoam and Middle Ear Injection of Methylprednisolone" in sudden sensorineural hearing loss

Protocol summary

Summary

This study is a clinical trial study conducted at Al- Zahra and Ayatollah Kashani hospitals of Isfahan in 2012 and 2013. The patients who entered in to the study were randomly assigned in two groups. In the first group sedation was used to lift up the ear flap through Transcanal method, then a Gelfoam soaked with methylprednisolone was placed on the site of Round Window and Gelfoam was placed on it. The second group of patients have intratympanic injection over the round window and received 3 doses of 0.5 cc dexamethasone with two days interval. After one month, patients in both groups are again assessed, and before and after intervention audiometries are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211062106N5**

Registration date: **2014-10-15, 1393/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

Afrooz Eshaghian

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1236 7247

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eshaghian@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of "intratympanic dexamethasone" with "Round Window Gelfoam and Middle Ear Injection of Methylprednisolone" in sudden sensorineural hearing loss

Public title

The comparative study of the effect of Intratympanic dexamethasone and dexamethasone in gelfom after myringotomy in sudden sensory neural hearing loss in Kashani and Al-zahra hospital in 2012-2013

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients with SSNHL who referred to the Al- Zahra and Ayatollah Kashani hospitals of Isfahan; no improvement in SSNHL with conventional treatments and systemic steroids; no pregnancy; no organ transplantation and patient satisfaction to participate in the study. Exclusion criteria: patients who failed to follow-up one month after treatment and the ones on

whom it was not possible to apply the treatment

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences , Hezarjarib St.

City

Isfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

444-14

Health conditions studied

1

Description of health condition studied

Hearing

ICD-10 code

H83.9

ICD-10 code description

Disease of inner ear, unspecified

Primary outcomes

1

Description

Hearing

Timepoint

Before intervention and one month after intervention

Method of measurement

Pure Tone Audiometry

Secondary outcomes

1

Description

Complication

Timepoint

During study

Method of measurement

Questioning about complication

Intervention groups

1

Description

Round Window Gelfoam and Middle Ear Injection of Methylprednisolone

Category

Treatment - Surgery

2

Description

intratympanic dexamethasone

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra medical center

Full name of responsible person

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Kashani medical center

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice challenry
Full name of responsible person
 Peyman Adibi
Street address
 Isfahan University of Medical Sciences , Hezarjarib st.
City
 Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Isfahan University of Medical Sciences, Vice challenry
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
 Isfahan University of Medical Sciences
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 Abbas Nadalinejhad
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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