

# 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

##### Email address

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

**Full name of responsible person**  
Abbas Nadalinejhad

**Position**  
Resident of ENT

**Other areas of specialty/work**

**Street address**  
Otolaryngology ward, Alzahra hospital, Sofe st.

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+98 31 3668 2525

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nadali.abbas@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences

**Full name of responsible person**  
Afrooz Eshaghian

**Position**  
resident

**Other areas of specialty/work**

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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*