

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Therapeutic effect of intra tympanic injection of Dexamethasone-Hyaluronic acid combination in comparison with intra tympanic Dexamethasone in sudden sensorineural hearing loss

#### Protocol summary

##### Summary

Sudden hearing loss is fairly a common disorder of unknown etiology which usually is treated by variety of drugs. Corticosteroids are used routinely as a main therapeutic agent via both systemic administration and/or intra tympanic injection. Since Hyaluronic acid is a safe and biocompatible substance that remains longer than Dexamethasone within middle ear cavity, this study was conducted and aimed to compare the effectiveness of intra tympanic injection of dexamethasone as a single drug with its combination with hyaluronic acid in patients with sudden sensorineural hearing loss. In this clinical trial that is being performed in Ayatollah Kashani Medical Center, Isfahan, Iran, 40 patients with diagnostic criteria of sudden hearing loss, were randomly assigned to two groups; 20 patients (one group) received 2.4 mg of intra tympanic dexamethasone while, in the other group the injection content were 2.4 mg of dexamethasone plus 2 mg of hyaluronic acid in combination. The volume of the syringes were equally adjusted by distilled water so that the surgeon is unaware about the kind of drug to be injected. Patients of both groups were injected every other day to the sum of three injections. Hearing status of patients have been evaluated by pure tone audiometry and defining the hearing thresholds of different frequencies, before and two weeks after the intervention. For enrolling the study, patients must be compatible to the medical definition of "sudden hearing loss" (at least 30 db loss in three successive frequencies in less than three days) and also the duration of hearing loss must not be more than one week, and also, their past medical history must be free of any otologic disorder in association with hearing loss or ear surgery. All patients have been undergone otoscopic examination the day after the last injection and one week later for detecting possible complications such as infection or tympanic membrane perforation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201611306699N3**  
Registration date: **2017-01-05, 1395/10/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-05, 1395/10/16

##### Registrant information

##### Name

Mehrdad Rogha

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3664 0352

##### Email address

rogha@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2017-02-18, 1395/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Therapeutic effect of intra tympanic injection of Dexamethasone-Hyaluronic acid combination in comparison with intra tympanic Dexamethasone in sudden sensorineural hearing loss

**Public title**

Effectiveness of intra tympanic injection of the mixture of Dexamethason+hyaluronic acid in the treatment of sudden hearing loss.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

The inclusion criteria consisted of unilateral hearing loss (occurring within 72 hours), the hearing threshold average greater than 50 dB, symptoms appearance within 7 days from our intervention, patient's pure tone audiogram at frequencies 250 500, 1000, 2000, 4000 and 8000 Hz, age range 18-80 years, lack of acoustic tumor, middle ear diseases, autoimmune diseases, vestibular problem (Menier disease&..), cardiovascular disorders and diabetes, no history of ear surgery and the patient's consent to participate in the study. Meanwhile patient's refusal to attend on time for follow up visits, any limitation to inject intra tympanum via external auditory canal such as stenosis, anatomical deformities and external and middle ear infections were considered as exclusion criteria.

**Age**From **18 years** old to **80 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jerib st,

**City**

Isfahan,

**Postal code****Approval date**

2015-12-29, 1394/10/08

**Ethics committee reference number**

lr.mui.rec.1394.3.756

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

Hearing loss

**ICD-10 code**

H91.2

**ICD-10 code description**

Sudden idiopathic hearing loss

**2****Description of health condition studied**

Sudden hearing loss

**ICD-10 code**

H91.2

**ICD-10 code description**

Sudden idiopathic hearing loss

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

Hearing threshold in different frequencies

**Timepoint**

Before &amp; two weeks after intervention

**Method of measurement**

Pure tone audiometry

**Secondary outcomes****1****Description**

Infection

**Timepoint**

One week after intervention

**Method of measurement**

Ear examination

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

In intervention group, patients receive three

intratympanic injections of 2 mg hyaluronic acid +2.4 mg Dexamethasone in combination.

**Category**

Treatment - Drugs

**2**

**Description**

The control group, receive three injections of 2.4 mg Dexamethasone intratympanically.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ayatollah Kashani Medical Center

**Full name of responsible person**

Dr.Amin Kalcoo

**Street address**

Kashani st,

**City**

Isfahan,

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Nematbakhsh

**Street address**

Hezar Jerib st.

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Isfahan 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**

Faculty of Medicine

**Full name of responsible person**

Dr. Amin Kalcoo

**Position**

Resident of Otolaryngology

**Other areas of specialty/work**

**Street address**

Kashani Medical Center,

**City**

Isfahan,

**Postal code**

**Phone**

+98 31 3233 0098

**Fax**

**Email**

Amin\_dr\_60@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Mehrdad Rogha

**Position**

Otolaryngologist

**Other areas of specialty/work**

**Street address**

Kashani Medical Center,

**City**

Isfahan,

**Postal code**

**Phone**

+98 31 3233 0098

**Fax**

**Email**

rogha@med.mui.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Mehrdad Rogha

**Position**

Otolaryngologist

**Other areas of specialty/work**

**Street address**

Kashani Medical Center,

**City**

Isfahan,

**Postal code**

**Phone**

+98 31 3233 0098

**Fax**  
**Email**  
rogha@med.mui.ac.ir  
**Web page address**

## 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*