

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

**The study of effectiveness of systemic Magnesium in treatment of sudden sensory neural hearing loss versus placebo in patient referred to ear nose and throat clinic of Taleqani hospital.**

### Protocol summary

#### Study aim

Evaluation of the effect of oral magnesium in the treatment of sudden sensorineural hearing loss

#### Design

Clinical trial with parallel intervention and control groups is performed in the two blind side of randomized blocks on 64 patients.

#### Settings and conduct

Patients are divided into intervention and control groups based on blocked randomization and given to participants the drug or placebo and the results are evaluated based on audiometry at the end of 2 weeks and end of the month

#### Participants/Inclusion and exclusion criteria

Patients with sudden sensory neural hearing loss without unestablished reason that have been identified for up to 15 days after the onset of the disease and have not received treatment and have been referred or referred to the ENT clinic of Taleghani Hospital.

#### Intervention groups

Intervention: in this study, the intervention group is given standard treatment of the disease and oral magnesium. The control group is given standard treatment and placebo.

#### Main outcome variables

Average hearing threshold

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200430047245N1**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

#### Registration date

2021-05-23, 1400/03/02

#### Registrant information

##### Name

Mohamad Taha Mehdi Araghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4486 3960

##### Email address

tahamehdiaraghi1990@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-04-24, 1400/02/04

#### Expected recruitment end date

2022-02-18, 1400/11/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The study of effectiveness of systemic Magnesium in treatment of sudden sensory neural hearing loss versus placebo in patient referred to ear nose and throat clinic of Taleqani hospital.

#### Public title

The study of effectiveness of systemic Magnesium in treatment of sudden sensory neural hearing loss versus placebo

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Affection to sudden sensory neural hearing loss The reason of sudden sensory neural hearing loss be idiopathic

### Exclusion criteria:

Referral after 1 month from the onset of the disease  
Contraindications to oral corticosteroids such as diabetes, hypertension, gastric ulcer or duodenum  
Evidence of systemic infectious or inflammatory diseases  
Coagulation disorders Other known causes of sudden sensory neural hearing loss

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocked randomization. According to the number of 64 samples in the randomization method, 8 blocks with 8 parts with the identifiers A, B, C, D, E, F, G, H are created, which We put in 4 of them drugs and the other 4 placebos with complete physical characteristics. The blocks are placed in the clinic after made them. And participants in the project are given a part of a block and patient information and number and part of the block will be recorded.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Double blind study. Due to the blocked randomization method, the participant and the researcher are blinded to the content of each block component. And participants do not know the content of the received block. And the researcher only records the patient information and the number and part of the delivered block and remains blind to the contents of the block throughout the treatment and study course.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Research Ethics Committee, School of Medicine, next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2021-02-15, 1399/11/27

#### Ethics committee reference number

IR.SBMU.MSP.REC.1399.717

## Health conditions studied

### 1

#### Description of health condition studied

Sudden sensory nueral hearing loss

#### ICD-10 code

H91.2

#### ICD-10 code description

Sudden idiopathic hearing loss

## Primary outcomes

### 1

#### Description

Average hearing threshold

#### Timepoint

Mean hearing threshold before the start of the study and 14 days after the intervention and the end of the month

#### Method of measurement

Audiometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, patients with sensorineural hearing loss undergo standard treatment with oral corticosteroids at a dose of 1 mg per kg body weight per day with 50 mg tablets of Iran hormon company and 250 mg magnesium oxide by Galinus company daily for 14 days. The treatment process is assessed by audiometry in Taleghani Hospital audiometry

center, before the start of treatment and at the end of the 14th day of treatment and the end of 1 month.

**Category**

Treatment - Drugs

**2****Description**

Control group: In this group, patients are treated with standard treatment with prednisolone with 50 mg tablets of Iran Hormone Company at a dose of 1 mg per kg body weight and microcrystalline cellulose placebo one tablet per day with a completely similar appearance to the main drug for 14 days .And the treatment process is assessed by performing audiometry in the audiometry center of Taleghani Hospital at the beginning of treatment and on the 14th day of treatment and at the end of 1 month

**Category**

Treatment - Drugs

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

Taleqani hospital Ent clinic

**Full name of responsible person**

Mohamad Taha mehdi araghi

**Street address**

Taleghani Hospital, next to Shahid Beheshti University of Medical Sciences, Erabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985711151

**Phone**

+98 21 2303 1505

**Fax**

+98 21 2243 2570

**Email**

taleghanihospital@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

Fifth Floor, Building No. 2, Shahid Arabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985711151

**Phone**

+98 21 2243 9331

**Email**

zarghi@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Personal cost of the project executor

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Taha Mehdi Araghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1469964383

**Phone**

+98 21 2303 1111

**Fax**

+98 21 2243 2570

**Email**

tahamehdiaraghi1990@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Taha Mehdi Araghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1469964383

**Phone**

+98 21 2303 1111

**Fax**

+98 21 2243 2570

**Email**

tahamehdiaraghi1990@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Taha Mehdi Araghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1469964383

**Phone**

+98 21 2303 1111

**Fax**

+98 21 2243 2570

**Email**

tahamehdiaraghi1990@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Patient audiometric files will be provided at the end of the project

**When the data will become available and for how long**

Access period starts 3 months after the results are published

**To whom data/document is available**

The data will be available to scientific researchers

**Under which criteria data/document could be used**

Data are available for further studies on sudden sensorineural hearing loss and magnesium effects

**From where data/document is obtainable**

To receive the data, correspond with the email of the project manager (Mohammad Taha Mehdi Araghi Email: Tahamehdiaraghi1990@gmail.com)

**What processes are involved for a request to access data/document**

After receiving the request for access to information from qualified people, the data will be sent within 1 week.

**Comments**