Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 assesed 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 assesd 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@gmaile.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