Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Prevalence of Dysgeusia After Surgical Treatment of Chronic Otitis Media and Evaluation of Therapeutic Effect of Gabapentin

Protocol summary

Study aim
Evaluation of the effect of gabapentin in the treatment of disgusia following ear surgery

Design
This study is a randomized clinical trial study with balanced block randomization method with a sample number of 170 cases, which is performed as a double-blind.

Settings and conduct
Patients with middle ear diseases who undergo surgery at Taleghani Hospital are evaluated for taste disorders with a questionnaire. The study is a double blind study.

Participants/Inclusion and exclusion criteria
Inclusion : All patients who have undergone surgery to treat a middle ear infection. Exclusion: History of systemic and peripheral diseases, psychiatric illness, metabolic disease, or a history of dysgeusia

Intervention groups
case: Patients in the intervention group receive a daily dose of 600 mg of gabapentin capsules (Razak Pharmaceutical Company) for 3 months. Control: Patients in the control group receive a placebo similar to the main drug.

Main outcome variables
taste؛

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200525047566N1**
Registration date: **2021-08-08, 1400/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-08, 1400/05/17**
Update count: **0**

Registration date
2021-08-08, 1400/05/17

Registrant information

Name
Arash Esmaeili

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4422 3777

Email address
arash.esmaeili@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-21, 1399/05/31

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Prevalence of Dysgeusia After Surgical Treatment of Chronic Otitis Media and Evaluation of Therapeutic Effect of Gabapentin

Public title
The effect of gabapentin on Dysgeusia after ear surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who have undergone surgery to treat a chronic otitis media are questioned for the complication of Dysgeusia.

Exclusion criteria:
history of systemic diseases central and peripheral neurological diseases psychiatric illness metabolic disease history of Dysgeusia

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **171**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the balanced block randomization method. Blocking is used in order to balance the number of samples assigned to each group. The size of all the blocks is equal and we will have 10 blocks of 6 cases (including 3 participants in an intervention group and 3 participants in the control group) in this trial. Software allocation Random is used for randomization. This software capable to generate random sequences by block generation method. For hiding we use concealment allocation in a way that before the individual is assigned, the assigned group is not specified. In this method, each of the random sequences created on a cards are placed in the closed envelopes. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the time of registration of participants, based on the order of entry of the eligible participants in the study, one of the closed envelopes will be opened and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
To reduce bias or bias related to the intervention and evaluation of the consequences, the method of double blind is used. In this method, the trial is planned in such a way that the participants do not know which of the two control or intervention groups he/she belongs to. Random blocks are also prepared by a person who is not involved in the treatment and are given to the therapist without informing the therapist.

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

Street address
No.15 ,3rd Allayi alley ,North Iranzamin St, Ponak

City
Tehran

Province
Tehran

Postal code
1476712345

Approval date
2021-02-15, 1399/11/27

Ethics committee reference number
IR.SBMU.MSP.REC.1399.723

Health conditions studied

1

Description of health condition studied
Dysgeusia

ICD-10 code
R43.8

ICD-10 code description
Other disturbances of smell and taste

Primary outcomes

1

Description
The amount of taste

Timepoint
After surgery and 3 months after treatment

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with disgusia receive a daily dose of 600 mg of gabapentin capsules (Razak Pharmaceutical Company) for 3 months.

Category
Treatment - Drugs

2

Description
Control group: Patients with disgusia will also take a placebo from Razak (which is very similar to gabapentin)

for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Arash Ismaili

Street address
No.15 ,3rd Allayi alley ,North Iranzamin St, Ponak

City
Tehran

Province
Tehran

Postal code
1476712345

Phone
+98 21 4461 8740

Email
arash.esmaeili@gmail.com

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
No.15 ,3rd Allayi alley ,North Iranzamin St, Ponak

City
Tehran

Province
Tehran

Postal code
1476712345

Phone
+98 21 4461 8740

Email
arash.esmaeili@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

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
Arash Esmaeili

Position
Otolaryngology head and neck surgery Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

Street address
Ashrafi esfahani Boulevard, nastaran st, Dastgheib st, madani gharbi Alley, number 7

City
Tehran

Province
Tehran

Postal code
1476712345

Phone
+98 21 4422 3777

Fax

Email
arash.esmaeili@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Arash Esmaeili

Position
Otolaryngology head and neck surgery Resident

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Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

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arash.esmaeili@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
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
3 months after printing the results

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
To review similar studies

From where data/document is obtainable
Send your request to the researcher's email to receive the data arash.esmaeili@gmail.com

What processes are involved for a request to access data/document
Data will be sent within 4 weeks after receiving the reques

Comments