

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

2021-08-08, 1400/05/17

Study aim

Evaluation of the effect of gabapentin in the treatment of dysgeusia 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:

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.

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

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

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

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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

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Otolaryngology head and neck surgery Resident

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Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Fax**Email**

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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
request

Comments