

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Study of the effect of neurofeedback sessions on reduction of tinnitus rate in patients with drug resistance Tinnitus

Protocol summary

Study aim

Determination of the effect of neurofeedback sessions on Tinnitus treatment

Design

Clinical trial is without a control group, without blinding and without randomization.

Settings and conduct

This is a clinical trial study in patients with Tinnitus referred to the ENT clinic of Alzahra and Kashani Hospitals of Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient has a subjective tinnitus; Age over 18; Have a natural hearing threshold; Exclusion criteria: Not consent to participate in the study at any time of the study

Intervention groups

The intervention group includes patients with drug-resistant tinnitus, who receive the use of Neurofeedback sessions as intervention. Neurofeedback sessions are designed by a psychiatrist and use the Tinnitus Software and Suite Document. This software has open display sessions so the psychiatrist decides when to end the sessions. The software is based on two scripts: the Tinnitus Training Script, based on the Dohman protocol, and the General Tinnitus Training Script designed by Linda Walker. The first one includes single feedback animation for 30 minutes, and the second one is a three ten-minute tasks with different animation feedbacks. In both ways, there are two minutes post and pre baseline. All scripts focus on parameters that include alpha / delta peak to peak ratio at f3, f4, fc1, fc2, and also in open display sessions associate with EEG assembly, other parameters such as alpha only, delta only, Gama only will be check.

Main outcome variables

The Tinnitus Handicap Inventory (THI) and the Visual Analogue Scale are completed before starting the neurofeedback for all of the patients. After the end of neurofeedback sessions, one month, three months and

six months afterwards, the patients again will complete this questionnaire and this scale will be completed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N30**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3629 1510

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mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Study of the effect of neurofeedback sessions on reduction of tinnitus rate in patients with drug resistance Tinnitus

Public title
Evaluation of the therapeutic effect of neurofeedback sessions on tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient has subjective Tinnitus -Age over 18 years
Have normal hearing threshold No neurological lesions such as epilepsy, Parkinson's and Alzheimer's

Exclusion criteria:
Any patient dissatisfaction to participate in the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
Isfahan University of Medical sciences, Hezar Jareeb street, Isfahan, Iran
City
Isfahan
Province
Isfahan

Postal code
8174675731

Approval date
2018-12-31, 1397/10/10

Ethics committee reference number
IR.MUI.MED.REC.1397.253

Health conditions studied

1

Description of health condition studied
Tinnitus

ICD-10 code
H93.1

ICD-10 code description
Tinnitus

Primary outcomes

1

Description
Tinnitus Handicap Inventory questionnaire scale

Timepoint
before starting the neurofeedback, After the end of neurofeedback sessions, one month, three months and six months afterwards

Method of measurement
Tinnitus Handicap Inventory questionnaire

2

Description
Visual Analogue Scale for Tinnitus in the ears of patients

Timepoint
before starting the neurofeedback, After the end of neurofeedback sessions, one month, three months and six months afterwards

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Based on inclusion and exclusion criteria, 30 patients with Tinnitus are selected who are resistant to medical treatments. Neurofeedback sessions are designed by a psychiatrist and use the Tinnitus Software and Suite Document.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Seyedeh Mahboube Nazari

Street address

Kashani Hospital, Kashani Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Mojtaba Abtahi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

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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 can be shared

When the data will become available and for how long

Immediately after publishing the study results

To whom data/document is available

For all who need this data

Under which criteria data/document could be used

Use of data is subject to copyright laws.

From where data/document is obtainable

Email the study manager to receive the data

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

Email the study manager to receive the data

Comments