Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Dorhman 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

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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

Isfehan

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

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Kashani Hospital, Kashani Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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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