

# 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)

##### Phone

+98 31 3629 1510

##### Email address

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

1435915371

**Phone**

+98 31 3386 6266

**Email**

kashani@mui.ac.ir

**Web page address**

<http://kashani.mui.ac.ir>

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Shaghayegh Haghjoo Javanmard

**Street address**

Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, Iran

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**Province**

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81746-73461

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+98 31 3792 3060

**Email**

sh\_haghjoo@med.mui.ac.ir

**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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manyekdoost@yahoo.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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### Person responsible for updating data

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Esfahan University of Medical Sciences

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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**