# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Study of the effect of binaural beat on clinical findings, psychoacoustic tests, EEG and ASSR 40 Hz on individuals suffering from annoying chronic tinnitus

## Protocol summary

**Study aim**
Investigation of the effect of binaural beat on clinical findings, psycho-acoustic tests, EEG and ASSR 40 Hz on annoying chronic tinnitus sufferers

**Design**
It is a clinical trial study without control group with 17 tinnitus patients.

**Settings and conduct**
After completing the consent form, hearing evaluations will be done in all participants (normal and tinnitus subjects). In the tinnitus group, psychoacoustic evaluations (tinnitus loudness and tinnitus pitch match), VAS-L and VAS-A (Visual Analogue Scale), THI, EEG and ASSR recording will be taken before and immediately after listening to binaural beat. This study will performed in audiology department of Iran University of Medical Science.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Right handed chronic nonpulsatile tinnitus subjects(>6 months); Age between 20 and 75 years; The behavioral pure-tone audiometry threshold levels of ≤20 dBHL in octave frequencies of 250–2000 Hz and not more than 40 dBHL in frequencies of 4000-8000 Hz Exclusion criteria: understanding the binaural beat ; having a remarkable cognitive problem and depression; taking of medications that affecting on central nervous system; having a history of otological, neurological, mental diseases, head trauma, psychiatric disorders, seizure.

**Intervention groups**
intervention group includes chronic tinnitus sufferers who will receive binaural beat stimuli intervention.

**Main outcome variables**
Tinnitus loudness; VAS-L; VAS-A ; THI; ASSR amplitudes; Mean frequency of EEG waves, EEG absolute & relative powers as main outcome measures and the tinnitus pitch as a secondary variable.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190507043508N1**
Registration date: **2019-06-10, 1398/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-10, 1398/03/20**
Update count: **0**

**Registration date**
2019-06-10, 1398/03/20

**Registrant information**

**Name**
Maryam Sadeghijam

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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maryamjam77@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-05-12, 1398/02/22

**Expected recruitment end date**
2019-09-13, 1398/06/22

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Study of the effect of binaural beat on clinical findings, psychoacoustic tests, EEG and ASSR 40 Hz on individuals suffering from annoying chronic tinnitus

**Public title**
The effect of binaural beat stimulation on treatment of chronic tinnitus

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Right-handedness Chronic nonpulsatile tinnitus (>6months) Age between 20 and 75 years Normal external and middle ear function and appearance using otoscopy and tympanometry Behavioral pure-tone audiometry threshold levels of ≤20 dBHL in octave frequencies of 250–2000 Hz and not more than 40 dBHL in frequencies of 4000 -8000 Hz Filling the study consent

**Exclusion criteria:**
Remarkable cognitive problems (MMSE over 20) Depression and anxiety (HADS scores less than 11 from 21 for either depressionand anxiety) A history of otological, neurological, mental diseases, head trauma, pregnancy, psychiatric disorders, dementia, seizure or any organic diseases that cause tinnitus Taking specific medication affecting on central nervous system The failure of understanding of binaural beat stimulation Tinnitus sufferers should not be simultaneously treated with other tinnitus treatments

**Age**
From **20 years** old to **75 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **17**

**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 Iran University of Medical Sciences

**Street address**
Milad Tower, Shiekh Fazlollah NouriShahid, Hemmat Highway

**City**
Tehran

**Province**
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**Postal code**
1449614535

**Approval date**
2017-04-17, 1396/01/28

**Ethics committee reference number**
IR.IUMS.REC1395.9211303211

## 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 loudness

**Timepoint**
Before and immediately after the treatment

**Method of measurement**
Audiometer instrument

### 2

**Description**
Tinnitus related loudness

**Timepoint**
Before and immediately after the treatment

**Method of measurement**
Visual Analogue Scale (VAS-L)

### 3

**Description**
Tinnitus related annoyance(distress)

**Timepoint**
Before and immediately after the treatment

**Method of measurement**
Visual Analogue Scale (VAS-A)

### 4

**Description**
Tinnitus Handicap Inventory

**Timepoint**
Before and immediately after the treatment

**Method of measurement**
Tinnitus Handicap Inventory Questionnaire

**5**

**Description**
The amplitude of auditory steady-state potentials
**Timepoint**
Before and immediately after the treatment
**Method of measurement**
Electroencephalography instrument

**6**

**Description**
Mean frequency of EEG waves
**Timepoint**
Before and immediately after the treatment
**Method of measurement**
Electroencephalography instrument

**7**

**Description**
EEG absolute powers
**Timepoint**
Before and immediately after the treatment
**Method of measurement**
Electroencephalography instrument

**8**

**Description**
EEG relative powers
**Timepoint**
Before and immediately after the treatment
**Method of measurement**
Electroencephalography instrument

## Secondary outcomes

**1**

**Description**
Tinnitus pitch
**Timepoint**
before and after treatment
**Method of measurement**
Audiometer instrument

## Intervention groups

**1**

**Description**
Intervention group: We have an intervention group in this study. All tinnitus patients will be treated by acoustic neuromodulation of binaural beat. They must listen to these stimuli for one month, 4 times a day, each time 15 minuets at predetermined times using personal hands free handsets or MP3 players at their most comfortable level (MCL). These stimuli are used by the MATLAB software and will be available to patients. In this study, we will use alpha binaural beat at 400 Hz frequency.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Audiology Department of Iran University of Medical Science
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
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Vice chancellor for research, Vice chancellor for International Affairs,Iran University of Medical Sciences, near Milad Tower, Shahid Hemmat Highway. Tehran
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**Web page 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**

Iran 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**

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Assistant Professor

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Ph.D.

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Audiology

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available