

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 be 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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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 depression and 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

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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 minutes 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

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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

Name of organization / entity
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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