Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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

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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 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
Tehran

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
Maryam Sadeghijam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran University of Medical Sciences

Full name of responsible person
Mahdi Akbari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Audiology

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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