Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The effect of a multisite transcranial random noise stimulation (tRNS) on tinnitus loudness, distress, mismatch negativity response (MMN) and electroencephalography (QEEG) in subjects with chronic tinnitus

Protocol summary

Study aim

Objectives: investigating the effects of a multisite transcranial random noise stimulation (tRNS) on tinnitus loudness, distress, MMN response and electroencephalography in chronic tinnitus subjects.

Design

Design: it is an interventional, one phase, and randomized, single blinded study. We have two groups: the intervention group in which we will apply the (high frequency) hf-tRNS over the right DLPFC (Dorso Lateral Prefrontal Cortex) followed by (low frequency) lf-tRNS over the auditory cortex in one session. And the control group in which we will apply the lf-tRNS over the auditory cortex only. Each patient in these two groups will take a placebo (Sham stimulation) session before the active tRNS session. There is randomization in allocating patients in groups, but they will take the two treatment stages (placebo & active) without randomization. Patients will be randomly organized into the two groups, but they will take the two treatment stages (placebo & active) without randomization i.e in all cases we will begin with the Sham stimulation. The way of randomization is by drawing a number between 1-32 where numbers from 1 to 16 is referring to the intervention group while numbers from 17 to 32 is referring to the control group. The randomization will be done by using Matlab.

Settings and conduct

Setting: After signing the consent form, Patients will be allocated randomly into two groups. In each group, each patient blindly will undertake both Sham and tRNS simulations beginning with the Sham one. Each patient will complete the VAS-L and VAS-A (Visual Analogue Scale) before and immediately after each session. In addition, EEG and MMN recording will be taken before and immediately after each session.

Participants/Inclusion and exclusion criteria

Participants: all patients with chronic nonpulsatile tinnitus (>6 months) can participate in this study with the following entry criteria: age between 20 and 50 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, and the tinnitus intensity moderate to severe; not having a remarkable cognitive problems, a previous formal musical training, or a history of otological, neurological, mental diseases, head trauma, psychiatric disorders, seizure and finally not having a pacemaker or defibrillator.

Intervention groups

Our intervention is applying transcranial random noise electrical stimulation with two protocols: multisite (auditory and prefrontal), and the auditory cortex. The placebo intervention is given by using the Sham stimulation mode; the current is switched off automatically after a ramp-in of 10 seconds and the session will be given in the same mentioned protocols in active interventions concerning electrode arrays and the time of the session which lasts for 20 minutes.

Main outcome variables

Tinnitus related loudness, tinnitus related annoyance (distress), MMN amplitude & MMN area under curve, Mean frequency of EEG waves, EEG absolute & relative powers and the EEG activity in ROIs (region of interest) as main outcome measures. The tinnitus pitch as a secondary variable.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017050724360N2**
Registration date: **2017-06-30, 1396/04/09**
Registration timing: **prospective**

Last update: **2017-12-14, 1396/09/23**
Update count: **1**

Registration date
2017-06-30, 1396/04/09

Registrant information

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Akram Pourbakht

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date
2017-06-01, 1396/03/11

Expected recruitment end date
2017-10-31, 1396/08/09

Actual recruitment start date
2017-07-15, 1396/04/24

Actual recruitment end date
2017-10-28, 1396/08/06

Trial completion date
empty

Scientific title
The effect of a multisite transcranial random noise stimulation (tRNS) on tinnitus loudness, distress, mismatch negativity response (MMN) and electroencephalography (QEEG) in subjects with chronic tinnitus

Public title
The effect of electrical stimulation on treatment of chronic tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Right-handedness Chronic nonpulsatile tinnitus (>6 months) Age between 20 and 50 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 Moderate to severe tinnitus intensity (THI score over 38-76)

Exclusion criteria:
Remarkable cognitive problems (MMSE over 20); Previous formal musical training 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; Having a pacemaker or defibrillator Taking specific medication that could modify the stimulation effect: (i.e., amine metabolism drugs: citalopram, sulpiride, and pergolide; amino acid metabolism drugs: lorazepam, rivastigmine. Moreover, voltage-sensitive channel blockers: carbamazepine and flunarizine).

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant

Sample size
Target sample size: **32**
Actual sample size reached: **33**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be simply randomized into two groups, but they will take the two treatment stages (placebo & active) without randomization i.e in all cases we will begin with the Sham stimulation. The way of randomization is by drawing a number between 1-32 where numbers from 1 to 16 is referring to the intervention group while numbers from 17 to 32 is referring to the control group. The randomization will be done by computer using Matlab.

Blinding (investigator's opinion)
Single blinded

Blinding description
All participants have no information about kind of their treatment session (placebo or real). They also have no information about in which group they are participating. However, the researcher knows these details and he is the performer of the experiment.

Placebo
Used

Assignment
Parallel

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
2017-04-22, 1396/02/02
Ethics committee reference number
IR.IUMS.REC 1395.9321667001

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 related loudness
Timepoint
Immediately after the treatment session
Method of measurement
Visual Analogue Scale (VAS-L)

2

Description
Tinnitus related annoyance(distress)
Timepoint
Immediately after the treatment session
Method of measurement
Visual Analogue Scale (VAS-A)

3

Description
MMN amplitude
Timepoint
Immediately after the treatment session
Method of measurement
MMN software

4

Description
MMN area under curve
Timepoint
Immediately after the treatment session
Method of measurement
MMN software

5

Description
Mean frequency of EEG waves
Timepoint
Immediately after the treatment session
Method of measurement
Mean frequency of EEG waves

6

Description
EEG absolute powers
Timepoint
Immediately after the treatment session
Method of measurement
EEG software

7

Description
EEG relative powers
Timepoint
Immediately after the treatment session
Method of measurement
EEG software

8

Description
EEG activity in ROIs (region of interest)
Timepoint
Immediately after the treatment session
Method of measurement
EEG software (sLORETA)

Secondary outcomes

1

Description
Tinnitus pitch
Timepoint
Before treatment
Method of measurement
Pitch matching

Intervention groups

1

Description
Control group: in this group the intervention is low frequency-tRNS with the same parameters used in the intervention group with one difference concerning the electrode array. In this concern the whole 20 minutes session will be applied over the auditory cortex (T3, T4). Before the active session the patient will take a sham stimulation session.
Category
Treatment - Devices

2

Description
Intervention group: Stimulation is delivered by a battery-

driven electrical stimulator (NeuroStim2; Medinateb, Iran) through conductive rubber electrodes, placed in two saline-soaked sponges. In the stimulation mode “noise” there is a random level of current generated for every sample (sampling rate 1280 samples/s). The random numbers are normally distributed; the probability density function follows a bell-shaped curve. In the frequency spectrum all coefficients have a similar size (“white noise”). The noise signal contains all frequencies up to half of the sampling rate, i.e., a maximum of 640 Hz. In our experiment this frequency spectrum is separated into a low (0.1–100 Hz)-frequency which will be applied over the auditory cortex (AC-tRNS) for 10 minutes followed by the high (101–640 Hz)-frequency spectrum stimulation of the DLPFC (DLPFC-tRNS) for the following 10 minutes to have an active stimulation session of 20 minutes called the multisite one. Because of the statistical characteristics, the signal has no DC offset, provided that the offset is set to zero and the intensity of alternating current is 2.0 mA which, is initially increased in a ramp-like fashion over several seconds (30 s) until reaching 2.0 mA. In the AC-tRNS, the electrodes is placed over the left and right auditory cortices (T3, T4), while in the DLPFC-tRNS they will be placed over the right DLPFC (F4) and the left frontopolar cortex (FP1) as determined by the International 10/20 Electroencephalogram System. In the stimulation mode “sham” the current is switched off automatically after a ramp-in of 30 seconds. Each patient in the group will take a sham stimulation session before taking his/her active intervention without knowing which of them is placebo. The session will be given in the same mentioned protocols in active intervention concerning electrode arrays and the time of the session.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
ENT and Head & Neck Research center, Iran University of Medical Sciences

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
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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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