

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Repeated sessions of transcranial direct current stimulation for the treatment of chronic subjective tinnitus

Protocol summary

Summary

Evaluating the effectiveness of repeated sessions of transcranial direct current stimulation for the treatment of subjective tinnitus, a double blind randomized controlled trial. subjects: Patients over 18 years of age; with chronic subjective tinnitus; lasting more than 6 month; without history of traumatic brain injury; intake of antipsychotic, antiepileptic, benzodiazepines stopped less than 1 month ago; cognition impairment; psychiatric disorder; pregnancy; previous experience of receiving tDCS. Sample size: 20 Intervention: transcranial direct current stimulation versus sham stimulation. Patients receive 5 sessions of real or sham stimulation. Outcome: change in tinnitus loudness or distress assessed with visual analog scale and Tinnitus Handicap Inventory (THI)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

"transcranial Direct Current Stimulation, tDCS"

IRCT registration information

IRCT registration number: **IRCT2014082018871N1**

Registration date: **2014-08-26, 1393/06/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-26, 1393/06/04

Registrant information

Name

Zohreh Sadat Mirshaki

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

Scientific title

Repeated sessions of transcranial direct current stimulation for the treatment of chronic subjective tinnitus

Public title

Evaluating effectiveness of transcranial direct current stimulation for treatment of tinnitus.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients over 18 years of age; with chronic subjective tinnitus; lasting more than 6 month
Exclusion criteria: Fluctuating audition; epilepsy; history of traumatic brain injury; intake of antipsychotic, antiepileptic, benzodiazepines stopped less than 1 month ago; intake of ototoxic medications; cognition impairment; psychiatric disorder including suicide attempt; cochlear implant; cardiac pacemakers; pregnancy; comorbidities interfering with intervention; previous experience of receiving tDCS

Age

No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science

Street address

Hemmat highway, between Sheykhfazlollah and Chamran h

City

tehran

Postal code

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

۹۳/۵/۱۰۵/۳۶۵

Health conditions studied

1

Description of health condition studied

tinnitus

ICD-10 code

H93.1

ICD-10 code description

tinnitus

Primary outcomes

1

Description

loudness of tinnitus

Timepoint

before and after each session, 2 weeks after last session

Method of measurement

visual analog scale

2

Description

distress resultinf from tinnitus

Timepoint

before and after evry session,2 weeks after last session

Method of measurement

visual analog scale

3

Description

disability resulting from tinnitus

Timepoint

before first session, immediately after last session, 2 weeks after last session

Method of measurement

Persian language version of the "Tinnitus Handicap Inventory"

Secondary outcomes

1

Description

any side effect

Timepoint

during, immediatelya after each session,2 weeks after last session.

Method of measurement

reported by patient

Intervention groups

1

Description

Intervention : for all patients the anode electrode is placed over the left temporoparietal area and the cathode electrode over right supraorbital area. during real stimulation 20 minutes of DC stimulation at 2 mA is delivered.

Category

Treatment - Devices

2

Description

for patients in control group, after placement of electrode the DC stimulator is turned on. after initial ramp up the device is turned off and the patient receive no more stimulation for the rest of the time. for all patients the device in placed out of sight, behind the subject

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Zohreh Mirshaki

Street address

Valiasr square, Behafarin street, Firoozgar hospital

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

bijan forough

Street address

Tehran, Valiasr square, Behafarin street, Firoozgar hospital

City

tehran

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 Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Zohreh Mirshaki

Position

phical medicine and rehabilitation resident/MD

Other areas of specialty/work

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty