

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Study of TDCS (Transcranial Direct Current Stimulation) on sleep quality improvement, changes in the expression of the hormone receptor gene and improving the quality of life of HIV + patients with sleep disorders

Protocol summary

Study aim

The Study of TDCS (Transcranial Direct Current Stimulation) on sleep quality improvement, changes in the expression of the hormone receptor gene and improving the quality of life of HIV + patients with sleep disorders

Design

The open label clinical trial

Settings and conduct

The patients with AIDS Emam Khomeyni Hospital are divided into two groups. Without blinded. Blood samples are taken from all of them to measure some factors Then performing the tDCS and sleep test in treatment group.

Participants/Inclusion and exclusion criteria

Having at least 18 years and maximum 50 years Ability to read and write Lack of psychotic disorders based on clinical interviews No use of hypnotic drugs A change of dose and the type of psychiatric medications of two months before entering the project until to end of the follow up period Not having history of Seizure Diagnostics one type of sleep disorders according to interviews and questionnaire Not having ulcer on the scalp Not having of heart battery

Intervention groups

There is one intervention group in this study, which is treated with tDCS, and the other group is the control , which is without intervention.

Main outcome variables

The study of treatment effect of sleep disturbance in tDCS method and hormone level ; gene Expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100601004076N25**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Mino0 Mohraz

Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 7984

Email address

minoomohraz@ams.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-19, 1399/01/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of TDCS (Transcranial Direct Current Stimulation) on sleep quality improvement, changes in the expression of the hormone receptor gene and improving the quality of life of HIV + patients with sleep disorders

Public title

The Study of TDCS on sleep quality improvement of HIV+ patients with sleep disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having at least 18 years and maximum 50 years Ability to read and write Lack of psychotic disorders based on clinical interviews No use of hypnotic drugs A change of dose and the type of psychiatric medications of two months before entering the project until to end of the follow up period Not having history of Seizure Diagnostics one type of sleep disorders according to interviews and questionnaire Not having ulcer on the scalp Not having of heart battery

Exclusion criteria:

Lack of desire to continue treatment Treating ECT from entering of the project to follow up period To use of hypnotic drugs from entering of the project to end of follow up period Having seizures from entering of the project to follow up period Exacerbation of symptoms of HIV that they may not continue to the project

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in two groups of test and control will be done by Block Balanced Randomization (BBR) method. The Randomization Sequence will be generated with using the free website at <http://www.randomization.com>

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Porsina Ave, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-01-24, 1398/11/04

Ethics committee reference number

IR.TUMS.VCR.REC.1398.839

Health conditions studied**1****Description of health condition studied**

Sleep Disorders

ICD-10 code

G47.8

ICD-10 code description

Other sleep disorders

Primary outcomes**1****Description**

Measurement of sleep quality

Timepoint

Before the onset of treatment and two weeks after starting treatment

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 12 sessions of tDCS treatment (2 mA, 20 minutes) treatment of sleep disorders

Category

Treatment - Devices

2**Description**

Control group: The control group does not receive the

intervention and receives routine treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran AIDS Research Center

Full name of responsible person

Maryam Salehi

Street address

End of Keshavar Blvd - Imam Khomeini Hospital
Complex- Back of Infection Building (Building 6) - Iran
AIDS Research Center

City

Tehran

Province

Tehran

Postal code

۷۳۳۱۴۱-۱۹-۱۴

Phone

+98 21 6658 1583

Email

ircha@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

Ms.Farhadi

Street address

Tehran Province, Tehran, Amir Abad, 5th St

City

Tehran

Province

Tehran

Postal code

13114-16846

Phone

+98 21 8216 1000

Email

support@insf.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran National Science Foundation

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Salehi

Position

Post - doctoral student

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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Email

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