Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Minoo 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 Treatmenting ECT fromentering 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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Latest degree

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Other areas of specialty/work

Neuroscience

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Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
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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