Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect and no effect of Treatment of sleep disorders on cognitive function, quality of life and CD4 + counts in people with HIV+ / AIDS

Protocol summary

Summary

This study is a double blind trial that aimed to determine the effect and no effect of Treatment sleep disorders on cognitive function, quality of life and CD4 + counts in people with HIV + / AIDS who are under treated with methadone. Inclusion criteria will be having a sleep disorder, Catching HIV + / AIDS, Being treated with methadone. Consumption of any drug or medication that causes sleep disturbances will be exclusion criteria. Statistical population will be included all patients with HIV + / AIDS who referred to methadone treatment centers to provide Methadone Maintenance Therapy in Kermanshah, Iran. At first, all participants will be interviewed and given some explanations about the project to them. After obtaining informed consent, these people will be enrolled. The statistical population will be included 60 patients. Based on the score that obtained in Pittsburgh Sleep Quality Index, Patients will be randomly divided into three groups of 20 randomly. All of them will respond to the Quality of Life and cognitive function scales; Also the number of CD4 + will be measured by flow cytometry. The first group will be treated with trazodone 25 to 100mg daily, the second group will be trained for sleep hygiene (two hours each time, weekly) and the third group will be a combination of sleep hygiene education and treatment with trazodone. All subjects in all three groups will be re-evaluated by completing mentioned questionnaires at baseline, 4 weeks and at the end of the study (8 weeks after baseline) and quality of life, cognitive function, CD4 + will be assessed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110923705N8**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

Mostafa Alikhani

Name of organization / entity

Kermanshah University of Medical Sciences - Substance Abuse Prevention Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-11-10, 1395/08/20

Expected recruitment end date

2017-11-10, 1396/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect and no effect of Treatment of sleep disorders on cognitive function, quality of life and CD4 + counts in people with HIV+ / AIDS

Public title

The effect of Treatment of sleep disorders on cognitive

function, quality of life and CD4 + counts in people with HIV+ / AIDS

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Having a sleep disorder; Patients treated with methadone; Having HIV+ / AIDS; Diagnose of sleep disorders by a psychiatrist that are not treated for sleep disorders. Exclusion criteria: Use of any drug or medication that impairs sleep; any other psychiatric and physical illness

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single 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 Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2016-07-13, 1395/04/23

Ethics committee reference number
kums.rec.1395.255

Health conditions studied

1

Description of health condition studied
HIV+/AIDS

ICD-10 code
B20

ICD-10 code description
Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases

Primary outcomes

1

Description
cognitive function

Timepoint
The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement
StroopTest

2

Description
quality of life

Timepoint
The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement
World health organization quality of life brief Scale

3

Description
CD4+

Timepoint
The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement
By Flow cytometry

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group 2, the participant will receive Sleep hygiene education(2 hours weekly). then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), ; And the quality of life, cognitive function, CD4 + count will be measured

Category
Behavior

2

Description

In the experimental group 1, the participant will receive trazodone drug 25 mg to 100mg daily. then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), ; And the quality of life, cognitive function, CD4 + count will be measured.

Category

Treatment - Drugs

3

Description

In the experimental group 3, the participant will be undertreated by a combination of treatment with trazodone and sleep hygiene education). then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), ; And the quality of life, cognitive function, CD4 + count will be measured

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Dr.Jalal Shakeri

Street address

Farabi Hospital, Isar square

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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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

Vice chancellor for research, Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Habib Allah Khazaie

Position

Psychiatrist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Phone
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Fax
Email
Web page address

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