Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effects of melatonin on depression and cognition function in hemodialyzed patients, A randomized, double-blind, controlled trial

Protocol summary

Study aim
Evaluation of melatonin effects on depression and cognition function in hemodialysed patients

Design
Clinical trial with community-based and pragmatic control group, with parallel, double-blind, randomized.

Settings and conduct
Participants undergoing dialysis in Taleghani Hospital of Urmia will be will be considered eligible for enrollment if they fulfill all the inclusion criteria and none of the exclusion criteria. After describing the details of the study, patients are required to sign the consent form. The relevant questions were asked before taking the medication. Anyone not involved in the intervention will randomize between the two groups of intervention and control It blocks by age and gender by computer, then assigns participants to the groups by code generated by the computer. They also package the medicine and placebo on the basis of the code. Another random sample It is unaware of the fact that it is not involved in the intervention, according to the code on the package, the medication is given to B. Marans are delivered

Participants/Inclusion and exclusion criteria
Including criteria: - Should be hemodialized for at least 3 months and 3 times per week and 4 hours per visit. - Should be fluent in Farsi. - They have visual and auditory health to complete the questionnaire. Excluding criteria: - Have diabetes type 1 or 2. - Psychotic diseases. -Take antidepressant medications Take anti-anxiety/sedative medications.

Intervention groups
Patients in the intervention group will receive 3mg melatonin daily for two months. In the control group, placebo will be administered with no markings, with color, shape, packaging, size, odor, and taste similar to the melatonin for the same duration

Main outcome variables
 Prevention and treatment of depression and cognitive impairment in patients undergoing dialysis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110226005914N3**
Registration date: **2019-02-19, 1397/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-19, 1397/11/30**
Update count: **0**

Registration date
2019-02-19, 1397/11/30

Registrant information

Name
Shima Hatamkhnai

Name of organization / entity
Tehran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of melatonin on depression and cognition function in hemodialyzed patients, A randomized, double-blind, controlled trial

Public title
Effects of melatonin on depression and cognition function in hemodialyzed patients, A randomized, double-blind, controlled trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
They should be hemodialized for at least 3 months and 3 times per week and 4 hours per visit. They should be fluent in Farsi language . They should have visual and auditory health to complete the questionnaire.

Exclusion criteria:
Have diabetes type 1 or 2. Have psychotic disease Take antidepressant medicationss. Take anti-anxiety/sedative medications.

Age
From **14 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization will be performed using a random number table generated by a computer software program and participants will be allocated to intervention or placebo group randomly. Also, the medicine and the placebo Packages are based on code. Another person who is unaware of the randomization and is not involved in the intervention, according to the code on the package, delivers the drugs to the patients.This randomization and assignment remain hidden from researchers and participants until the completion of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blocked randomization will be performed using a random number table generated by a computer software program and participants will be allocated to intervention or placebo group randomly. Also, the medicine and the placebo Packages are based on code. Another person who is unaware of the randomization and is not involved in the intervention, according to the code on the package, delivers the drugs to the patients.This randomization and assignment remain hidden from researchers and participants until the completion of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Emergency Alley, Resalat street

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2017-12-11, 1396/09/20

Ethics committee reference number
IR.UMSU.REC.1396.247

Health conditions studied

1

Description of health condition studied
Chronic kidney disease, Hemodialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Depression Score in the Beck Questionnaire.Cognitive impairment Score in the MMSE Questionnaire.

Timepoint
Before starting the medication and two months after taking Melatonin tablets.

Method of measurement
Beck Depression questionnare and MMSE Cognitive Impairment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive melatonin at a dose of 3 mg per day for two months.
Category
Treatment - Drugs

2

Description
Control group:In the control group, patients are given a placebo with no markings, with the same color, shape, packaging, size, odor, and taste, are given at the same dose as melatonin for the same duration
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital of urmia
Full name of responsible person
Sepideh Roshan
Street address
Emergency Alley, Resalat street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebi
Street address
Emergency Ave, Resalat Blvd, urmia
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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
Oroumia 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
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Shima Hatamkhani
Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Not familiar with the procedure

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Some of the data related to the principal outcome

When the data will become available and for how long
following publishing the article

To whom data/document is available
all the data will be available via publishing the article

Under which criteria data/document could be used
Depends on the case

From where data/document is obtainable
Emailing to the corresponder

What processes are involved for a request to access data/document
article request

Comments