

# 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 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 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 hemodialyzed 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 Hatamkhani

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2208 5548

##### Email address

hatamkhani@razi.tums.ac.ir

##### 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 hemodialyzed 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 medications. 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 questionnaire 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

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 4897

##### Email

hatamkhani@razi.tums.ac.ir

## 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

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

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#### Email

hatamkhani@razi.tums.ac.ir

#### 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

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Shima Hatamkhani

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Clinical Pharmacy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Shima Hatamkhani

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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 responder

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

article request

**Comments**