

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Assessment of the effect of oral melatonin on the quality of life and sleep and blood pressure of kidney failure patients in the hemodialysis departments of Yasouj city: a randomized clinical trial.

#### Protocol summary

##### Study aim

Assessment of the effect of oral melatonin on the quality of life and sleep and blood pressure of kidney failure patients in the hemodialysis departments of Yasouj city: a randomized clinical trial.

##### Design

A placebo-controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 82 patients. A simple randomization method using a table of random numbers will be used.

##### Settings and conduct

This study will be conducted in the hemodialysis center of Yasouj city. After obtaining informed consent, the patients will be randomly divided into two groups of 41 people receiving 3 mg of melatonin or placebo at night. The duration of the study will be 6 weeks. Grouping of patients will be based on A and B codes, and the patient or therapist will not know about the grouping of patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include age over 18 years, the ability to give informed consent, and the duration of hemodialysis of at least three months. Exclusion criteria include peritoneal dialysis, known major illness (malignancy, uncontrolled infection, uncontrolled heart failure), pregnancy, acute medical or surgical illness requiring hospitalization or surgery, severe psychological illness (severe depression, psychosis, dementia), and a history of sensitivity to melatonin.

##### Intervention groups

In the intervention group, patients receive 3 mg of melatonin orally at night. In the placebo group, patients receive a starch tablet at night.

##### Main outcome variables

Quality of sleep; quality of life; blood pressure during dialysis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230205057333N1**

Registration date: **2023-03-15, 1401/12/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-15, 1401/12/24**

Update count: **0**

##### Registration date

2023-03-15, 1401/12/24

##### Registrant information

##### Name

Arash Iranmanesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 0166

##### Email address

rozina.abasi@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-04-21, 1402/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Assessment of the effect of oral melatonin on the quality of life and sleep and blood pressure of kidney failure patients in the hemodialysis departments of Yasouj city: a randomized clinical trial.

## Public title

The effect of oral melatonin on the quality of life, sleep and blood pressure of renal failure patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age above 18 years Ability to give informed consent The duration of hemodialysis is at least 3 months

### Exclusion criteria:

Peritoneal Dialysis Known major disease (malignancy, uncontrolled infection, uncontrolled heart failure) pregnancy Acute medical or surgical illness that requires hospitalization or surgery severe psychological illness (severe depression, psychosis, dementia) History of sensitivity to melatonin

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **82**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method in this study is a simple randomization type. Patients are examined individually for randomization. For randomization, each person is assigned a number from 1 to 82. Then, by reading the table of random numbers from left to right, odd numbers are considered for the intervention group and even numbers are considered for the placebo group. From patient number 1 to 82, according to the number of random numbers table (even or odd), they are entered into the intervention or placebo group. This means that when reading the table of random numbers, the first number will be for patient number 1, the second number will be for patient number 2, and so on, based on whether the number in the table of random numbers is odd or even, the patients are divided into the above-mentioned two groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the patient and the clinical caregiver are unaware of the group (intervention/placebo), and the groups are named groups A and B. The researcher and supervisor are aware of the intervention and placebo groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

##### Street address

Shahid Motahari St., Vice President of Research, Yasouj University of Medical Sciences

##### City

Yasouj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

#### Approval date

2023-01-30, 1401/11/10

#### Ethics committee reference number

IR.YUMS.REC.1401.163

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease (CKD)

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

At the beginning of the study and at the end of the sixth week

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire (PSQI)

### 2

#### Description

Quality of Life

#### Timepoint

At the beginning of the study and at the end of the sixth week

#### Method of measurement

Quality of Life Questionnaire of Kidney Patients (KDQOL - SF™ 1/3)

### 3

#### **Description**

blood pressure

#### **Timepoint**

At the beginning of study, at the end of the third and sixth week

#### **Method of measurement**

In all patients, systolic and diastolic blood pressure during dialysis will be measured and recorded using erka sphygmomanometer.

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Taking 3 mg of oral melatonin at night / Hakim Pharmaceutical Company, for six weeks

#### **Category**

Treatment - Drugs

#### 2

#### **Description**

Control group: Taking starch tablets at night for six week

#### **Category**

Placebo

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Yasouj Hemodialysis Center, Imam Sajjad Hospital

##### **Full name of responsible person**

Arash Iran Manesh

##### **Street address**

Shahid Motahari Boulevard, Hemodialysis Center of Yasouj University of Medical Sciences

##### **City**

Yasouj

##### **Province**

Kohgiluyeh-va-Boyerahmad

##### **Postal code**

759174147

##### **Phone**

+98 74 3334 6078

##### **Email**

sisacohortpersian@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Yasouj University of Medical Sciences

##### **Full name of responsible person**

Seyyed Amin Hosseini Mutlaq

##### **Street address**

Motahari St., Research and Technology Vice-Chancellor

##### **City**

Yasuj

##### **Province**

Kohgiluyeh-va-Boyerahmad

##### **Postal code**

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##### **Phone**

+98 74 3334 6078

##### **Email**

aminhomo@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

##### **Full name of responsible person**

Arash Iranmanesh

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Internal Medicine

##### **Street address**

Emam sajjad hospital

##### **City**

Yasuj

##### **Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Arash Iranmanesh  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**

Arash Iranmanesh

**Position**  
Resident  
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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**  
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**  
No - There is not 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