

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyyed Amin Hosseini Mutlaq

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Motahari St., Research and Technology Vice-Chancellor

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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

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

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Person responsible for updating data

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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