Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of melatonin on sleep quality and anxiety in hemodialysis patients

Protocol summary

Study aim

The aim of this study was to investigate the effect of melatonin drug therapy on sleep quality and anxiety levels in patients and compare it with the control group. changes in sleep quality using the Pittsburgh Sleep Quality Questionnaire (PSQI) and anxiety levels using the GAD-7 questionnaire will be evaluated and analyzed before and after drug intervention.

Design

The present study is a controlled clinical trial with a two-group design (intervention and control) and pre- and post-intervention evaluation, which will be conducted prospectively.

Settings and conduct

It will be conducted voluntarily and with informed consent from the participants. The study will be conducted in the dialysis ward of Imam and Golestan Hospital. All participant information will be kept confidential and no identifying information will be recorded.

Participants/Inclusion and exclusion criteria

Age 18 years and older, at least 6 months of hemodialysis, PSQI score greater than 5 (indicating poor sleep quality), GAD-7 score greater than 5 (indicating anxiety), no use of melatonin or other sleeping pills in the past 3 months Severe neurological disorders or psychiatric illnesses under treatment, use of medications that affect melatonin metabolism (such as fluvoxamine) Uncontrolled heart failure, active malignant diseases, severe infections, need for emergency or surgical interventions during the study, PSQI score less than 5 or GAD-7 score less than 5 during the study

Intervention groups

Intervention group: receiving melatonin according to the instructions specified in the study protocol. Control group: receiving usual treatment (without melatonin). Both groups will be homogenized in terms of demographic variables and study entry conditions.

Main outcome variables

Sleep quality based on the Pittsburgh Sleep Quality Questionnaire (PSQI) total score Anxiety level based on the Generalized Anxiety Disorder (GAD-7) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251127068128N2**
Registration date: **2026-01-30, 1404/11/10**
Registration timing: **prospective**

Last update: **2026-01-30, 1404/11/10**
Update count: **0**

Registration date

2026-01-30, 1404/11/10

Registrant information

Name

Shahla Ahmadi Halili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 681 6124

Email address

ahmadihalili-sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-04, 1404/11/15

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of melatonin on sleep quality and anxiety in hemodialysis patients

Public title

The effect of melatonin on sleep quality and anxiety in hemodialysis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older At least 6 months of hemodialysis history PSQI score above 5 (indicating poor sleep quality) GAD-7 score greater than 5 (indicating the presence of anxiety) Not taking melatonin or other sleep medications in the past 3 months

Exclusion criteria:

Having severe neurological disorders or psychiatric illnesses under treatment Taking medications that affect melatonin metabolism (such as fluvoxamine) Uncontrolled heart failure Active malignant diseases Severe infections Need for emergency or surgical interventions during the study PSQI score less than 5 or GAD-7 score less than 5 during the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the inclusion and exclusion criteria, eligible patients are randomly assigned to two groups: intervention (receiving melatonin) and control (without drug intervention) in a 1:1 ratio using a simple random number table.

Blinding (investigator's opinion)

Not 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 Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences، Koi Golestan، Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Approval date

2026-01-10, 1404/10/20

Ethics committee reference number

IR.AJUMS.REC.1404.556

Health conditions studied

1

Description of health condition studied

End-stage chronic renal failure treated with hemodialysis

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

2

Description of health condition studied

Sleep quality disorders in hemodialysis patients

ICD-10 code

G47.0

ICD-10 code description

Insomnia

3

Description of health condition studied

Sleep quality disorders in hemodialysis patients

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

sleep quality

Timepoint

At baseline and 6 weeks after intervention

Method of measurement

The questionnaire consists of 9 questions and assesses 7 components of sleep quality. The total score ranges from 0 to 21; a higher score indicates poorer sleep quality. A score greater than 5 indicates sleep disturbance.

2

Description
Anxiety Severity
Timepoint
Before the start of the intervention 6 weeks after the start of the intervention
Method of measurement
The questionnaire consists of 7 questions with a 4-point Likert scale (0 to 3) and the total score ranges from 0 to 21. Higher scores indicate more severe anxiety. A score of more than 5 indicates the presence of anxiety.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patients in this group include 28 people who take 3 mg of melatonin every night 30 minutes before bedtime. The treatment period is 6 weeks and the aim of this intervention is to examine the effects of melatonin on sleep quality in hemodialysis patients.
Category
Treatment - Drugs

2

Description
Control group: The patients in this group, which consists of 28 people, will not receive any drug intervention. This group is intended to examine the effect of melatonin compared to the natural sleep and anxiety patterns of hemodialysis patients.Initially, patients will be given a sleep disorder and anxiety disorder questionnaire.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital., Dialysis Unit
Full name of responsible person
Shahla Ahmadi Halili
Street address
ers from Imam Khomeini Hospital., Dialysis unit
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 916 681 6124
Email
ahmadihalili-sh@ajums.ac.ir

2

Recruitment center
Name of recruitment center
Golestan hospital., Dialysis unit
Full name of responsible person
Shahla Ahmadi Halili
Street address
Koi golestan., Golestan hospital., Dialysis unit
City
Ahvaz
Province
Khouzestan
Postal code
6135733117
Phone
+98 916 681 6124
Email
ahmadihalili-sh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdollah Rafiei
Street address
24 metery street, East sahely highway, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 916 681 6124
Email
ahmadihalili-sh@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Shahla Ahmadi Halili

Position
Assistant Professor of Nephrology

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Azadegan St., 24 meters from Imam Khomeini Hospital

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
0612222922

Email
ahmadihalili-sh@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Shahla Ahmadi Halili

Position
Assistant Professor of Nephrology

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Other areas of specialty/work
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Street address
Azadegan., 24 meters., imam khomeini hospital

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 916 681 6124

Fax

Email
ahmadihalili-sh@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Shahla Ahmadi Halili

Position
Assistant Professor of Nephrology

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Province
Khouzestan

Postal code
6193673166

Phone
+98 916 681 6124

Fax

Email
ahmadihalili-sh@ajums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available