

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effect of Melatonin on Sleep Quality and Cognitive Function of Hemodialysis Patients

Protocol summary

Study aim

The effect of melatonin on sleep quality and cognitive function of hemodialysis patients

Design

A parallel, randomized controlled clinical trial will be performed on 102 hemodialysis patients referred to the Sari Citizen Dialysis Center. Blocking method is used for randomization.

Settings and conduct

The study population in this study will be 102 hemodialysis patients referred to Sari Shahrivand Dialysis Center. Participants in the present study are divided into two groups. 51 placebo participants and the next 51 participants will be given melatonin. The results of both groups will be collected separately and compared at the end.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People 18 years and older with insomnia problem, hemodialysis for more than 6 month, no hearing and vision problems, the patient can give informed consent . exclusion criteria: Patients taking anti-anxiety or hypnotic drugs, the patient has an active infection, the patient is pregnant or breastfeeding, the patient has uncontrolled diabetes

Intervention groups

Intervention group: Patients in the intervention Group will receive 3 mg of Melatonin at Night, half an hour before bedtime for 6 Weeks. The questionnaire will be completed by the Patient herself or with the help of a Nurse at the beginning of the Study and after 6 weeks in the Group that received Melatonin Control group. At the same time, in the control group, people receive a placebo half an hour before bedtime

Main outcome variables

Measuring the sleep quality of patients undergoing hemodialysis, measuring the cognitive functions of patients undergoing hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211030052917N1**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**

Update count: **1**

Registration date

2021-12-14, 1400/09/23

Registrant information

Name

Marzie Salehi Hikoui

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Melatonin on Sleep Quality and Cognitive Function of Hemodialysis Patients

Public title

The Effect of Melatonin on sleep quality and cognitive function of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People 18 years and older The patient should not involved in any other research project The patient can give informed consent Hemodialysis for more than 6 months The patient has a Pittsburgh sleep quality index score higher than 5 The patient has a Montreal cognitive function index score lower than 26 The patient has adequate vision and hearing The patient has normal thyroid tests

Exclusion criteria:

The patient has already taken melatonin The patient has a history of taking sleeping pills The patient has a history of taking any drugs The patient has an active infection The patient is pregnant or breastfeeding The patient has uncontrolled diabetes The patient has dementia The patient has liver disorders The patient has cerebrovascular disorders The patient needs immediately Intervention for Hospitalization and surgery The patient has heart failure The patient has iron deficiency anemia Patients taking anti-anxiety or hypnotic drugs due to neuropsychiatric disorders

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a randomized, double-blind clinical trial. The randomization method is through blocking. The randomization unit in this study is individual and the randomization tool is done through statistical software. Randomization will be done using Random allocation software. Samples are allocated in 17 blocks of six. That means 6 patients are placed in each block. Three patients are in the intervention group and the other three are in the control group

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a randomized, double-blind clinical trial. All Dialysis patients participating in this study and the person distributing the drug They do not know which is Placebo to and which ones are Melatonin And only the supervising researcher knows about it. Participants in the

present study are divided into two Groups. 51 Participants will be in the Intervention Group and the next 51 will be in the Control Group. After selecting the Samples with inclusion Criteria, the blocking Method will be used for Random Allocation. After creating Random Numbers with the mentioned Software, the Blocking list is provided to the main Executor And the Samples will be entered into the Study accordingly. Patients in the intervention group will receive 3 mg of melatonin at night, half an hour before bedtime for 6 weeks. The packaging of placebo drugs is the same as melatonin in terms of shape, size, color and smell, and the way of receiving placebo will be the same as the intervention group. The results of both groups will be collected separately and compared at the end.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Mazandaran University of Medical Sciences

Street address

Mazandaran, Sari, Amir Mazandarani St., Shahband St., Mehdiabad St., Nasibeh School of Nursing and Midwifery

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Mazandaran

Postal code

4815733971

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.MAZUMS.REC.1400.10563

Health conditions studied**1****Description of health condition studied**

The effect of melatonin on sleep quality and cognitive function in hemodialysis patients

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Patients' sleep quality Score on the Pittsburgh Sleep Quality Assessment Tool

Timepoint

Measurement of Sleep Quality at the beginning of the Study (before the intervention) and immediately after the intervention in the intervention Group and Control Group

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

Patients' cognitive Function score in the Montreal Cognitive Assessment Tool

Timepoint

Measurement of cognitive Functions at the beginning of the Study (before the intervention) and immediately after the intervention in the intervention Group and Control Group

Method of measurement

Montreal Cognitive Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention Group will receive 3 mg of Melatonin (Razak Company, 3 mg per tablet) at Night, half an hour before bedtime for 6 Weeks. The questionnaire will be completed by the Patient herself or with the help of a Nurse at the beginning of the Study and after 6 weeks in the Group that received Melatonin. While obtaining the satisfaction of participating in the Study and emphasizing the use of drugs and the absence of side effects And by sending a short message to the Participants or a Member of the patient's family in this research, Patients are reminded about taking medicine.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive a placebo for 6 weeks, half an hour before bedtime. The packaging of placebo drugs is the same as melatonin in terms of shape and size, and the way of receiving Placebo will be the same as the intervention Group. While obtaining the satisfaction of participating in the study and emphasizing the absence of Side effects And By sending a short message to the participants or a member of the patient's family in this study, Patients are reminded about taking Placebo. The placebo will be made

by Razak company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrvand Kidney Patients Center

Full name of responsible person

Dr. Farhad Gholami

Street address

Mazandaran - Sari, Keshavarz Boulevard, Keshavarz 44, Shahrvand Kidney Patients Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Marzie Salehi Hikoui

Position

Msc. Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Person responsible for updating data

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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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

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