

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of melatonin on sleep disturbances of hemodialysis patients.

Protocol summary

Summary

The aim of this clinical trial is to evaluate the effect of melatonin administration on sleep disorders in patients undergoing hemodialysis in Arak Valiasr Hospital. At first step for all of the patients who meet the inclusion criteria (age 18-85, no disability for communication and willing to participate) PSQI sleep quality questionnaire will be completed. According to this survey patients who have scores above 5 will be assuming to have sleep disorder. After obtaining informed written consent, these patients randomly will allocate in 2 groups (case and control). Case and placebo groups are going to receive melatonin (3mg shiff manufacturer) and placebo every night for 6 weeks, respectively. A 3-day washout will precede the switch from melatonin to placebo or vice versa. The sleep quality score, lipids profile (LDL, HDL, total Cholesterol, TG), Hemoglobin and recieved erythropoietin doses will be measured at the beginning, 6w and 12w in both arms. Statistical analysis will perform using SPSS 17.0 and two-sample paired-group t test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108077253N1**

Registration date: **2011-10-15, 1390/07/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-15, 1390/07/23

Registrant information

Name

Mahnaz Edalat-nejad

Name of organization / entity

Arak university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1417 3630

Email address

hosseintabar@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on sleep disturbances of hemodialysis patients.

Public title

The effect of melatonin on sleep disturbances of hemodialysis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ESRD patients undergoing hemodialysis >3 months with PSQI score equal or >5/ age:18-85/capable of giving informed consent exclusion: severe allergy to melatonin/unstable angina or hearth failure class 4/ pregnancy or breast feeding/ severe medical or psychological disease/history of melatonin consumption

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alamalhoda st.

City

Arak

Postal code

Approval date

2011-06-15, 1390/03/25

Ethics committee reference number

90-109-9

Health conditions studied

1

Description of health condition studied

Chronic Renal Failure

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

2

Description of health condition studied

Sleep disturbance

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention and 6th and 12th week of intervention.

Method of measurement

PSQI questionnaire

Secondary outcomes

1

Description

Serum lipids

Timepoint

At study beginning, 6 and 12 weeks

Method of measurement

Valiasr lab

2

Description

Erythropoitin dosages

Timepoint

0, 6th and 12th weeks

Method of measurement

Providing from dialysis sheets review

3

Description

Serum hemoglobin levels

Timepoint

0, 6th and 12th weeks

Method of measurement

Valiasr lab

Intervention groups

1

Description

Tab melatonin 3mg/day. every night at 8 pm for 6 weeks.

Category

Treatment - Drugs

2

Description

Tab placebo(melatonin placebo). every night at 8 pm for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr.Mahnaz Edalat-nejad

Street address

Valiasr hospital, Valiasre squire.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office of Vice Chancellor for Research of Arak Medical Science University

Full name of responsible person

Dr.Saeed Changizi Ashtiyani

Street address

Arak University of Medical Sciences, Sardasht st.

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Office of Vice Chancellor for Research of Arak Medical Science University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Tahereh Hossein-tabar

Position

Internal medicine assistant/ assistant

Other areas of specialty/work

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Internal medicine department, Valiasr hospital.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Edalat-nejad. Mahnaz

Position

Assistant professor in adult nephrology

Other areas of specialty/work

Street address

Internal medicine department-nephrology ward, Valiasr hospital.

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Edalat-nejad.Mahnaz

Position

Nephrologist/Assistant professor

Other areas of specialty/work

Street address

Internal medicine department- Nephrology ward, Valiasr hospital.

City

Arak

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty