

# 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**

**Street address**

Internal medicine department, Valiasr hospital.

**City**

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+98 86 1417 3630

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hosseintabar@arakmu.ac.ir

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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**

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**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*