

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The study of the effects of melatonin on nocturnal blood pressure fluctuation in patients with obstructive sleep apnea

#### Protocol summary

##### Study aim

Investigating the effects of melatonin on nocturnal blood pressure fluctuations in patients with obstructive sleep apnea

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase one and two on 60 patients.

##### Settings and conduct

Sixty participants will randomly assign to the melatonin or placebo group by 1:1 ratio. Patients will receive 3 mg melatonin orally in a single dose or placebo, 1 h before bedtime. All measurements including polysomnography and laboratory assessments will conduct at baseline and after one month of melatonin therapy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria will as follows: (1) age between 18 and 75 years; (2) Diagnosis of OSA [apnea-hypopnea index (AHI)  $\geq 15$ ]; and (3) BP  $\leq 180/110$  mmHg. Exclusion criteria are (1) patients who have been hospitalized for cardiac or respiratory exacerbations less than 6 weeks prior to recruiting; (2) those with autonomic nervous system diseases or endocrine disorders which might influence BP; (3) BP  $\geq 180/110$  mmHg; and (4) those unwilling to participate in the study.

##### Intervention groups

Intervention group: receiving 3 mg of melatonin as a single dose one hour before sleep Control group: receiving placebo as a single dose one hour before sleep

##### Main outcome variables

Polysomnography assessment; blood samples will analyze for serum ACE level and cortisol.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221023056278N1**

Registration date: **2023-06-03, 1402/03/13**

Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**

Update count: **0**

##### Registration date

2023-06-03, 1402/03/13

##### Registrant information

###### Name

Mohammad Rasoul Ghadami

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3826 5255

###### Email address

mr\_ghadami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-06, 1402/03/16

##### Expected recruitment end date

2023-11-06, 1402/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The study of the effects of melatonin on nocturnal blood pressure fluctuation in patients with obstructive sleep apnea

##### Public title

The study of the effects of melatonin on nocturnal blood

pressure fluctuation in patients with obstructive sleep apnea

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 18 and 75 years Diagnosis of OSA [apnea-hypopnea index (AHI)  $\geq$  15] BP  $\leq$  180/110 mmHg

### Exclusion criteria:

Patients who have been hospitalized for cardiac or respiratory exacerbations less than 6 weeks prior to recruiting Those with autonomic nervous system diseases or endocrine disorders which might influence BP BP  $\geq$  180/110 mmHg Those unwilling to participate in the study.

## Age

From **18 years** old to **75 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization will be done in a simple way using a sealed envelope in which the name of the intervention group is written.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the people who were invited to participate in the study and were classified into intervention groups after obtaining informed consent, as well as the person who analyzed the data collected during the study, did not aware about the prescribed medicine.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

NIMAD

##### Street address

Fatemi St., the beginning of Baath St

##### City

Tehran

#### Province

Tehran

#### Postal code

1419693211

#### Approval date

2021-11-30, 1400/09/09

#### Ethics committee reference number

IR.NIMAD.REC.1400.163

## Health conditions studied

### 1

#### Description of health condition studied

Obstructive sleep apnea

#### ICD-10 code

G47.33

#### ICD-10 code description

Obstructive sleep apnea (adult) (pediatric)

## Primary outcomes

### 1

#### Description

Systolic and diastolic BP, serum ACE level and cortisol

#### Timepoint

Before and one month after the intervention

#### Method of measurement

Using polysomnography and laboratory evaluation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Thirty participants will randomly assign to the melatonin group. Patients will receive 3 mg melatonin (time release) orally in a single dose or placebo, 1 h before bedtime. All measurements including PSG and laboratory assessments will conduct at baseline and after one month of melatonin therapy.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 30 participants are randomly placed in the control group. Patients will receive placebo orally in a single dose, 1 hour before bedtime. All measurements, including PSG and laboratory evaluations, were performed at baseline and after one month of placebo treatment.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sleep Disorders Research Center

**Full name of responsible person**

Dr. Habibolah Khazaie

**Street address**

Dolat abad, Farabi hospital

**City**

Kermanshah

**Province**

Kermanshah

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6719851451

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+98 83 3826 5255

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**Email**

hakhazaie@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

NIMAD

**Full name of responsible person**

Dr. Younes Panahi

**Street address**

Fatemi St., the beginning of Baath St

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**Phone**

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**Email**

nimadiran@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

NIMAD

**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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Rasoul Ghadami

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Dolat abad, Farabi hospital

**City**

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mr\_ghadami@yahoo.com

## Person responsible for scientific inquiries

#### Contact

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Kermanshah University of Medical Sciences

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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**

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