Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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) ≥ 15]; and (3) BP ≤ 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 ≥ 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) ≥ 15] BP ≤ 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 ≥ 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
NIMAD
Full name of responsible person
Dr. Younes Panahi
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Fatemi St., the beginning of Baath St
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1419693211
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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
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Person responsible for updating data

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Position
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Latest degree
Specialist
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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