Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effects of Melatonin on Sleep Quality and Cognitive Function of Shift Workers with Sleep Disorder: A Randomized, Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim
Determining the effects of melatonin on sleep quality and cognitive performance of resident physicians with sleep disorders following shift work

Design
A controlled, parallel-group, double-blind, randomized, phase 2-3 clinical trial on 70 patients. The rand function of Excel was used for randomization.

Settings and conduct
The study is conducted in the Psychiatric Research Center of Roozbeh Hospital in an outpatient setting on shift workers with sleep disorder. Seventy patients will be randomly divided into melatonin or placebo groups with blocks of four and will be evaluated in terms of sleep quality, occupational cognitive failures, and side effects at baseline and weeks 1 and 4. Allocated group numbers will be kept in sealed and opaque envelopes to conceal the treatment from patients and the research team, and melatonin and placebo are exactly matched.

Participants/Inclusion and exclusion criteria
Resident physicians with night shift jobs aged 25 to 55 who had at least seven night shifts during the last month, have a plan to spend seven night shifts during the study, complain of sleep disorder after shift, and have poor sleep quality are included in the study. Complaints of sleep disturbance during normal sleep hours, pregnancy/its intention and breastfeeding in female participants, history of sensitivity or occurrence of complications after taking melatonin and its agonists, and And the history of thyroid, cardiovascular, kidney, and endocrine diseases and psychiatric disorders (except sleep disorders) lead to non-inclusion. Additionally, working fewer than six night shifts (i.e., zero to five shifts) during the study month resulted in exclusion.

Intervention groups
For the participants of the intervention and control groups, melatonin 5mg and placebo, respectively, are prescribed half an hour before bedtime following the night shift for one month.

Main outcome variables
Sleep Quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N153**
Registration date: **2023-07-22, 1402/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-22, 1402/04/31**
Update count: **0**

Registration date
2023-07-22, 1402/04/31

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-22, 1402/04/31

Expected recruitment end date

2023-08-29, 1402/06/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Melatonin on Sleep Quality and Cognitive Function of Shift Workers with Sleep Disorder: A Randomized, Double-Blind, Placebo-Controlled Trial

Public title

The effect of Melatonin for sleep and function of shift workers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being a resident physician with night shift work Age between 25 and 55 years Working at least seven night shifts in the past month Having an schedule to work at least seven night shifts during the study month Complaining about sleep disturbance after shift work and poor sleep quality (Cut-off value greater than 4 in shortPSQI)

Exclusion criteria:

Complaining about sleep disturbance during normal sleeping hours (always and not related to the night shift) Pregnancy, breastfeeding or intention to become pregnant in female participants History of sensitivity or side effects after taking melatonin and its agonists History of thyroid, cardiovascular, kidney, and endocrine diseases and psychiatric disorders (except sleep disorder) Working less than six night shifts during the study month

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization using A and B blocks in a 1:1 ratio will be done with n=4: AABB, ABAB, ABBA, BABA, BAAB, BBAA The blocks were randomly used to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

An independent group will perform randomization, allocation concealment, and blinding procedures. The allocated group numbers will be kept confidential in sequentially numbered, sealed, and opaque envelopes to conceal treatment assignments from patients, healthcare providers, outcome assessors, and the research team. Melatonin and matched placebo are identical in size, shape, color, smell, and taste.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Directorate of Health, Rescue and Treatment of Police Headquarter of I

Street address

Valiasr St

City

Tehran

Province

Tehran

Postal code

1417944661

Approval date

2023-07-06, 1402/04/15

Ethics committee reference number

IR.SBMU.TEB.POLICE.REC.1402.009

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Sleep Quality

Timepoint

Baseline, Week 1, and Week 4

Method of measurement

Short Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description
Occupational Cognitive Failure
Timepoint
Baseline, Week 1, and Week 4
Method of measurement
Occupational Cognitive Failure Questionnaire

2

Description
Side effects
Timepoint
Baseline, Week 1, Week 4, and whenever the participant experiences a complication, by phone
Method of measurement
Checklist of side effects in which the side effects of melatonin are clearly reported, and it is possible for the participant to report other side effects that are not included in it

Intervention groups

1

Description
Intervention group: Melatonin (C13H16N2O2) in the form of tablets with a dose of 5 mg produced by Jalinous Pharmaceutical Company, administered orally 30 minutes before the person's desired time to sleep at night after shift work for one month
Category
Treatment - Drugs

2

Description
Control group: Placebo in tablet form, completely similar to the medication in terms of shape, color, smell and taste produced by Jalinous Pharmaceutical Company
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Ahmad Shamabadi
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South Kargar St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Department of Health, Rescue and Treatment of I.R.Iran Police Force, Applied Research Center
Full name of responsible person
Reza Mohammadi
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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
Department of Health, Rescue and Treatment of I.R.Iran Police Force, Applied Research Center
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
Department of Health, Rescue and Treatment of I.R.Iran Police Force, Applied Research Center
Full name of responsible person
Sajad Khanjani
Position
Head of Research Center for Cognitive & Bihavioral Science
Latest degree

Ph.D.

Other areas of specialty/work
Psychology

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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