

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effect of melatonin and placebo on the quality of sleep in patients admitted in Post Coronary Care Unit

Protocol summary

Summary

The current protocol was aimed to compare the effect of melatonin and placebo on the quality of sleep in patients admitted in Post Coronary Care Unit. In overall, 110 patients were participated in the study. Patients were randomly allocated into two groups of intervention and control using block allocation method (block size 4). The intervention group received a 3 mg melatonin tablet 30 minutes before bedtime at night for two weeks. The control group also received a 3 mg placebo tablet included chickpea flour 30 minutes before bedtime at night. The placebo tablet was made in the same form and size with the melatonin tablet. It was double blind study that person who evaluates sleep quality and also patients were not aware of participation assigned to groups. An inclusion criterion was as follow: patients admitted in post coronary care unit that their sleep questionnaires score were more than fifteen. Exclusion criteria were considered as: chronic pain; psychology disorder; using sedative medications. Quality of sleep was evaluated by using of Petersburg sleep quality questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081010340N18**

Registration date: **2017-09-04, 1396/06/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

Mohammad Aryaie

Name of organization / entity

Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of melatonin and placebo on the quality of sleep in patients admitted in Post Coronary Care Unit

Public title

The effect of melatonin on the quality of sleep

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients admitted in post coronary care unit that their sleep questionnaires score were more than fifteen. Exclusion criteria : chronic pain; psychology disorder; using sedative medications.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Golestan University of Medical Sciences

Street address

Falsafi educational campus, Vice Chancellor of Technology and Information, 4 Kilometer of Gorgan-sari Road, Gorgan

City

Gorgan

Postal code**Approval date**

2017-08-06, 1396/05/15

Ethics committee reference number

IR.GOUMS.REC.1396.83

Health conditions studied**1****Description of health condition studied**

Sleep Disorder

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

Primary outcomes**1****Description**

Sleep quality

Timepoint

Before intervention and 14 day after intervention

Method of measurement

Petersburg sleep quality questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group received a 3 mg melatonin tablet 30 minutes before bedtime at night for two weeks.

Category

Treatment - Drugs

2**Description**

The control group also received a 3 mg placebo tablet included chickpea flour 30 minutes before bedtime at night for two weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Mehran Mahyar

Street address

Shahid Sayyad Shirazi Hospital, Shahid Sayyad Shirazi Street, Gorgan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Mohsen Saeedi

Street address

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City

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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

Golestan University of Medical Sciences

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

Golestan University of Medical Sciences

Full name of responsible person

Mehran Mahyar

Position

General Practitioner

Other areas of specialty/work

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MSc in Epidemiology

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Mehran Mahyar

Position

General Practitioner

Other areas of specialty/work

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