

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

aryaie@goums.ac.ir

##### 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

**City**

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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**

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

**City**

Gorgan

**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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Mohamma Aryaie

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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**

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**Other areas of specialty/work**

**Street address**

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