

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effects of Ear Plug and Eye Mask on Nocturnal Sleep Quality in Patients of Cardiac Intensive Care Unit

Protocol summary

Summary

This controlled clinical trial study will conduct to determine the effectiveness of ear plug and eye mask on nocturnal sleep quality in patients of Cardiac Intensive Care Unit. Firstly, the level of noise and light will be monitored for 24 hours in two random days in CCU. 68 patients will select via convenience sampling, then the subjects will allocate into four groups (three intervention groups and a control group) by using stratified random allocation. Intervention will be take place on patients with IHD at second night of hospitalization in CCU. On second night, all subjects (intervention and control groups) will complete Verran and Snyder-Halpern Sleep Scale (VSH Sleep Scale) and the level of melatonin and cortisol will be measured. Eye mask, ear plug and both eye mask and ear plug will be used respectively for three intervention groups on third night. After intervention, the level of melatonin and cortisol will be measured for all subjects, and sleep scale will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061717237N2**
Registration date: **2014-10-15, 1393/07/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

Mahnaz Modanloo

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research & Technology, Golestan University of Medical Sciences

Expected recruitment start date

2014-03-18, 1392/12/27

Expected recruitment end date

2015-03-18, 1393/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Ear Plug and Eye Mask on Nocturnal Sleep Quality in Patients of Cardiac Intensive Care Unit

Public title

The Effects of Ear Plug and Eye Mask on Patients' Nocturnal Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 65 years old, consciousness, orientation to time and place, have no sleep disorders, have no visual and hearing problem, the absence of psychiatric disorders, have no history of night-shift work at least in past 3 years, no use of coffee, alcohol and hypnotic medication at least 12 hours before the study time. Exclusion criteria: Occurrence of sleep disorders during study period (such as sleep apnea, narcolepsy, restless leg syndrome), use of hypnotic

medication during study period, the onset of menstruation in female patients during the study, patients who will be discharged or died during the study, sleeping confounding medications (e.g., opiates, amphetamines), receive tranquilizers and anesthetics, cardiopulmonary resuscitation during the study.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization strategies: Considering age, gender and cause of hospitalization, patients were allocated to three matched intervention groups (eye mask, ear plug and both eye mask and ear plug) and control group. Allocation will be achieved using stratified random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee

Street address

Deputy of Research and Technology, Golestan
University of Medical Sciences (Falsafi Complex),
Hirkan Boulevard, Gorgan

City

Gorgan

Postal code

4934174515

Approval date

2014-03-18, 1392/12/27

Ethics committee reference number

394592122510

Health conditions studied

1

Description of health condition studied

Ischaemic Heart Diseases

ICD-10 code

I24

ICD-10 code description

Other acute ischemic heart diseases

Primary outcomes

1

Description

Sleep

Timepoint

Before and a day after intervention

Method of measurement

Verran and Snyder Halpern Sleep Scale

Secondary outcomes

1

Description

Melatonin

Timepoint

Before and a day after intervention

Method of measurement

The measurement of urinary melatonin

2

Description

Cortisol

Timepoint

Before and a day after intervention

Method of measurement

The measurement of urinary cortisol

Intervention groups

1

Description

Eye Mask Group: For this group of patients, in addition to routine care, eye mask (made of black cloth) will be used from 22 pm on the third day of hospitalization to 7 am of next day.

Category

Prevention

2

Description

Ear Plugs Group: For this group of patients, in addition to routine care, the ear plug (Elvex Mark. Quattro model, four-step .lace) will be used from 22 pm on the third day of hospitalization to 7 am of next day.

Category

Prevention

3

Description

Ear Plugs and Eye Mask Group: For this group of patients, in addition to routine care, eye mask and ear plug will be used from 22 pm on the third day of hospitalization to 7 am of next day simultaneously.

Category

Prevention

4

Description

Control group, without any intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Medical & Educational Center

Full name of responsible person

Gholam Ali Riahi

Street address

Amiralmomenin Medical Center, Mirza Kochak Khan street, Kordkuy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology

Full name of responsible person

Masood KhoshNia

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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

Deputy of Research and Technology

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

Somayeh Rezvani Khorshidi

Position

MS Student of Critical Nursing Care

Other areas of specialty/work

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PhD

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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