Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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Sponsors / Funding sources

1

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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

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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