

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effects of using earplugs and eye masks on sleep quality in coronary care unit (CCU)

Protocol summary

Summary

Sleep disturbance is depends on a couple of factors such as noise, light and dark cycle disorder in cardiac care unit(CCU) that can lead to acute coronary syndrome and worsen the patients' condition. One of these important factors is environmental. Sleep can be improved by reducing physical milieu. Although many studies have been working on sleep disorder there is little focus on removing bothering environmental features. This study was designed to compare the effects of simple and low cost devices such as eye mask and earplugs with each other on reducing the environmental factors and improving sleep in CCU patients. This study is a randomized clinical trial conducted in Imam Khomeini Hospital of Jiroft in 2011. Patients were randomly divided into three groups: eye mask, earplugs and both eye mask and earplugs users. Crossover method was used; so that half of the patients in each group were assumed control for themselves the first night and the other half on the second night. The day after VSH-scale was filled at 9 am by participants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205139731N1**

Registration date: **2012-11-25, 1391/09/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-25, 1391/09/05

Registrant information

Name

Fateme Mashayekhi

Name of organization / entity

Jiroft University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences, Neuroscience Research Center

Expected recruitment start date

2011-08-11, 1390/05/20

Expected recruitment end date

2011-12-19, 1390/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of using earplugs and eye masks on sleep quality in coronary care unit (CCU)

Public title

The effects of using earplugs and eye masks on sleep quality in coronary care unit (CCU)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 18 years; Alert and aware of the time and place; Able to respond VSH-scale (Sleep quality). Exclusion criteria: Having chronic sleep disorders; Get sleep medications and intravenous narcotics and general anesthesia in 12 hours before the study; Hearing and vision problems.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics Committee of vice chancellor for research,
Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of
Medical Sciences, Jahad street

City

Kerman

Postal code**Approval date**

2011-10-19, 1390/07/27

Ethics committee reference number

k/90/8

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

Sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

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

Sleep disorder

Timepoint

The night before the intervention and after the
intervention (9 am)

Method of measurement

VSH-scale

Secondary outcomes**1****Description**

Sleep disorders

Timepoint

The night before the intervention and after the
intervention (9 Am)

Method of measurement

VSH-scale

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

Using eye masks

Category

Prevention

2**Description**

Using earplugs

Category

Prevention

3**Description**

Using earplugs and eye masks

Category

Prevention

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

Cardiac care unit (CCU), Imam Khomeini Hospital of
Jiroft

Full name of responsible person

Fateme Mashayekhi

Street address

Jiroft University of Medical Sciences

City

Jiroft

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Dr. Malekpour Afshar

Street address

Jahad street

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Jiroft University of Medical Sciences

Full name of responsible person

Fateme Mashayekhi

Position

MSc in Nursing, Critical Care

Other areas of specialty/work

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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