

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

Protocol summary

Summary

Sleep disturbance 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. One of the important factors is environment. 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 Afshar Hospital of Yazd in 2014. 90 Patients were randomly divided into three groups: eye mask, earplugs and both eye mask and earplugs users. VAS scale at the beginning and end of stay in ICU will be completed by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407127875N4**

Registration date: **2015-02-16, 1393/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-16, 1393/11/27

Registrant information

Name

Hossein Rahmani

Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

Public title

The effect of use of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 25 years; Alert and aware of the time and place; Able to respond scale, EF up to 40%. 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 **25 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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences,
safaie, yazd

City

yazd

Postal code

Approval date

2014-03-18, 1392/12/27

Ethics committee reference number

17/1/257636/P

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

F99

ICD-10 code description

Mental disorder, not otherwise specified

Primary outcomes

1

Description

sleep quality

Timepoint

At the beginning and end of stay in CCU

Method of measurement

verbal analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Using earplugs and eye masks

Category

Prevention

2

Description

Using eye masks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Afshar Hospital

Full name of responsible person

Street address

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Saduqi University of Medical Sciences

Full name of responsible person

vice chancellor for research of Shahid Saduqi
University of Medical Sciences

Street address

Shahid Saduqi University of Medical Sciences , safaieh

City

yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Saduqi 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

Shahid Saduqi University of Medical Sciences

Full name of responsible person

zahra fahim raouf

Position

master of science

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