Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of red light on the quality of sleep of patients hospitalized in the cardiac intensive care unit

Protocol summary

Study aim
Determining the effect of red light on the sleep quality of patients admitted to the intensive care unit of the heart

Design
A community based, pragmatic, control group clinical trial was randomized with parallel groups, on 80 patients.

Settings and conduct
Sleep disorders are a common problem in heart patients. One of the complementary medicine methods for treating sleep disorders is the use of red light. This clinical trial will be conducted in the cardiac intensive care units of Beheshti Hospital in Kashan without blinding. In the intervention group, patients will be exposed to red light for two vonsecutive nights from 22:00 to 06:00. In the control group, there will be no intervention. Patients will complete the standard sleep quality questionnaire of saint mary's hospital in the morning of the first day before the intervention and then in the morning of the first and second day after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: admission letter and cardiologist's consent, age 30 to 75 years, ability to speak and understand and alert, no Intubation, no severe heart failure; Exclusion criteria: unwillingness to continue the research, incomplete answers to the questionnaires, discharge earlier than the end of the intervention, transfer from the ward, cardiopulmonary resuscitation, non observance of light conditions

Intervention groups
Intervention group: the Light emitted from an infrared lamp with a red filter without visible light of 50 watts with a wavelength of more than 700 NM , while the curtains of the patient's room will be drawn and movement will be limited to the patient's room; It will take place for 2 consecutive nights from 22:00 to 6:00 in the morning. In the control group, there is no change in the room light.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111210008348N53**
Registration date: **2024-04-30, 1403/02/11**
Registration timing: **prospective**

Last update: **2024-04-30, 1403/02/11**
Update count: **0**

Registration date
2024-04-30, 1403/02/11

Registrant information

Name
Neda Mirbagher

Name of organization / entity
Kashan University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-04, 1403/02/15

Expected recruitment end date
2024-11-05, 1403/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of red light on the quality of sleep of patients hospitalized in the cardiac intensive care unit

Public title
Investigating the effect of red light on the sleep quality of cardiac patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Admission letter from the cardiologist and the consent of the attending physician to perform the Intervention Age between 30 and 75 years Written consent of the Individual to enter the study Patients who are able to speak and understand the language and are alert At least 24 hours have passed since hospitalization No intubation Absence of severe heart failure Minimum MMSE score equal to 22

Exclusion criteria:
Reluctance to continue participating in research Incomplete answers to questionnaires Discharge earlier than the end of the intervention Moving from the department (such as performing a procedure in the operating room, etc.) Performing cardiopulmonary resuscitation Failure to comply with the conditions related to the change of light

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
For the sampling method, first the elegible Ssmples will be selected as available and using computer software on the sealed envelope website by placing the number of groups and the total uumber of samples and the number of samples in each block (the total number of samples is 80 people and the number of samples in each block is 8 people) a list of 10 rapndom blocks will be prepared, in each block, 4 people from each group will be placed.

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
Ethics committee of nursing and midwifery school, Kashan University of Medical Sciences

Street address
School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2024-04-14, 1403/01/26

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1403.005

Health conditions studied

1

Description of health condition studied
Heart disease

ICD-10 code
I51

ICD-10 code description
Complications and ill-defined descriptions of heart disease

Primary outcomes

1

Description
Sleep quality

Timepoint
Before the intervention, 1 and 2 days after the intervention

Method of measurement
Saint Mary's Hospital Sleep Quality Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: for 2 consecutive nights, from 10:00

PM to 6:00 AM, the room lamps will be turned off and to prevent the white light from the corridors, the room curtains will be drawn and movement will be limited to the patient's room. So, with the reading light which has an infrared lamp with a red filter without visible light, 50 watts with a wavelength of more than 700 NM, Lucky herp brand, the light in the room will be changed to red light.

Category
Other

2

Description
Control group: There is no Change in the Light of the Room

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital, Kashan

Full name of responsible person
Seyed Mehdi Motahary Barzoki

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Shahid Beheshti Hospital, Kashan University of Medical Sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Gholam Ali Hamidi

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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Kashan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Neda Mirbagher Ajorpaz

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data of Participants are Confidential
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable