Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of using and without using eye mask and earplugs on sleep quality, incidence of delirium, Physiological parameters and length of stay for patients admitted to the CCU

Protocol summary

Summary

Present study aims to investigate the effects of using blinders and earplugs on sleep quality, range of Delirium incidence and physiologic parameters among patients admitted CCU. It is a clinical experimental study. 80 patients with cardiac problems were selected as samples randomly and divided into 3 treatment groups and one control group. Intervention started by having the first group using blinders, the second one earplug, and the third both blinders and earplugs from the second night attending hospital. Using standard questionnaires (CCU, dizziness evaluation), Petsburg sleep quality, Delirium outbreak and, also, physiological parameters were evaluated while the patients were staying at the hospital. No instruction was included among control group.Inclusion study: recognizing time; place and people; having no operation; having no visual or auditory problems; not using psychic medicine; having no mental disorders; having no known sleeping disorders; no addiction to drugs; not having disorders affecting sleeping such as migraine; staying CCU for at least 3 days; least GCS equal to 12; not having the patient intubed. Exclusion indexes: having serious problems being in CCU; quitting the study on patients will; cardiac-pulmonary revival throughout the study; receiving drugs which affect night sleep such as duretics ; prescribing sedative drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122914333N14**
Registration date: **2014-01-17, 1392/10/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-17, 1392/10/27

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-07-22, 1393/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using and without using eye mask and earplugs on sleep quality, incidence of delirium, Physiological parameters and length of stay for patients admitted to the CCU

Public title

The effect of using eye mask and earplugs on sleep

quality, incidence of delirium, Physiological parameters and length of stay for patients admitted to the CCU of Imam Ali Hospital in Kermanshah in 2013

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion study: recognizing time; place and people; having no operation; having no visual or auditory problems; not using psychic medicine; having no mental disorders; having no known sleeping disorders; no addiction to drugs; not having disorders affecting sleeping such as migraine; staying CCU for at least 3 days; least GCS equal to 12; not having the patient intubed. Exclusion indexes: having serious problems being in CCU; quitting the study on patients will; cardiac-pulmonary revival throughout the study; receiving drugs which affect night sleep such as duretics ; prescribing sedative drugs.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not 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

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2013-12-21, 1392/09/30

Ethics committee reference number

407797/420/پ

Health conditions studied

1

Description of health condition studied

Nonorganic sleep disorders

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

Primary outcomes

1

Description

Sleep quality

Timepoint

Beginning and end of attending hospital

Method of measurement

According to Pitsburg questionnaire

2

Description

Delirium range

Timepoint

Daily, since the second day of attending till leaving hospital

Method of measurement

According to dizziness evaluation questionnaire NEE CHAM

3

Description

During attending hospital

Timepoint

Leaving hospital

Method of measurement

According to patient profile

4

Description

Blood pressure

Timepoint

Daily during attending hospital

Method of measurement

Using an automatic pressure check equipment while seating from left arm

5

Description

Temperature

Timepoint

Daily during attending hospital

Method of measurement

Using a mercury thermometer in mouth

6

Description
Heart beats
Timepoint
Daily during attending hospital
Method of measurement
Using monitoring tools

7

Description
Breath counts
Timepoint
Daily during attending hospital
Method of measurement
Chest movement counts by an expert in one minute

8

Description
SPO2
Timepoint
Daily during attending hospital
Method of measurement
Using pals eximeter

9

Description
Consciousness level
Timepoint
Daily during attending hospital
Method of measurement
Considering three visual, verbal and motor response parameters

Secondary outcomes

empty

Intervention groups

1

Description
Intervention in the first treatment group included using blinders from 10 pm to 7 am since the second night of attending CCU.
Category
Treatment - Other

2

Description
Intervention in the second treatment group included using earplugs from 10 pm to 7 am since the second night of attending CCU.
Category
Treatment - Other

3

Description
Intervention in the third treatment group included using both blinders and earplugs from 10 pm to 7 am since the second night of attending CCU.
Category
Treatment - Other

4

Description
There is no intervention in control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Hospital
Full name of responsible person
Shahin Elyasianfar
Street address
CCu ,Emam Ali Hospital,Boulevard Shahid Beheshti
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Reza Pourmirza Kalhori

Position
Ms.of Nursing training

Other areas of specialty/work

Street address
First of Dolatabad Boulvard,Eisar Square

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Kermanshah

Postal code

Phone
+98 83 1827 9304

Fax

Email
pourmirza@kums.ac.ir

Web page address

Person responsible for updating data

Contact

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