

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 diuretics ; 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

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

Email address

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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 diuretics ; 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 pulse oximeter

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

Korosh 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 Boulevard,Eisar Square

City

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