Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of the effect of white noise, earplug and Instrumental music on sleep in CCU patients

Protocol summary

Summary

The aim of this study is comparing the influence of white music, earplug, music without lyrics on patients' sleeping who were in CCU. This study is done in 2014 with 144 participants. They were hospitalized in C.C.U. in Tehran University of Medical Sciences hospitals. These participants had these characteristics. being in C.C.U at least for three nights because of coronary syndrome, obtaining score 5 or higher in sleeping quality questionnaire (sleeping disorder); homodynamic stability; not taking addictive drugs 5 or 6 hours before sleeping; not taking any anti-depressants, inotrope, amphetamine during the night; not having hearing disorder and not using ways affecting sleeping. Participants were put in control and experimental group randomly. Participants having sever problems were out of study. The problems were as follows; homodynamic instability, unconsciousness, need to mechanical ventilation, cardiac pulmonary arrest. Patients in experimental group, received white music, earmuffs, music without lyrics that induces sleep. In order to measure quality and quantity of patients sleeping in this study. Petersburg sleeping quality questioners, Demographics form, sleeping quantity questioners(sleep log) are used and then 4groups are compared with each other.

General information

Acronym
Sleep and cardiac patients

IRCT registration information
IRCT registration number: **IRCT201403138286N4**
Registration date: **2014-09-15, 1393/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2014-09-15, 1393/06/24

Registrant information
Name
Fatemeh Bahramnezhad
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2014-07-01, 1393/04/10
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
Comparative study of the effect of white noise, earplug and Instrumental music on sleep in CCU patients

Public title
Comparative the effect of white noise, earplug and Instrumental music on sleep in Cardiac patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: willing to cooperate and

complementing a questionnaires; obtaining score 5 or higher in sleeping quality questionnaire (sleeping disorder); being at least 30 years old; being in C.C.U at least for three nights because of coronary syndrome; time and place awareness; homodynamic stability; no breathing problem; having no surgery; not taking addictive drugs 5 or 6 hours before sleeping; not taking any anti-depressants; inotrope; amphetamine during the night. Not taking nerve drugs; not having obvious sleeping disorder; not having brain disorder; not having hearing disorder; not having maladies affecting sleeping such as migraine and Arthritis rheumatoid; not using effective methods of sleep. Exclusion criteria: unwillingness to cooperate and completing questionnaires; appearance of sever problems e.g. hemodynamic instability, unconsciousness, mechanical ventilation, cardiac pulmonary arrest, during the study; leaving hospital before 3 days; emergency prescribed drugs such as addictive drug, anesthesia drug, diuretics, anti-depressants, inotrope, sedative and amphetamine during the night.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **144**

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
Ethical Review Commiitee of Tehran University of Medical Sciences

Street address
Central Building, Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City
Tehran

Postal code
-

Approval date
2014-06-18, 1393/03/28

Ethics committee reference number
130/673/93/د

Health conditions studied

1

Description of health condition studied
Heart disease(acute coronary system)

ICD-10 code
I20-I25

ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
Sleep quantity

Timepoint
In this study, sleeping quantity in starting of sleeping, when they are awake or nap, and sleeping hours in the first day in hospital and during these 3 days are measured

Method of measurement
Sleeping quantity questioners(sleep log)

2

Description
Sleep quality

Timepoint
In the first day of hospital and 3 days after that

Method of measurement
Petersburg questioner

Secondary outcomes

empty

Intervention groups

1

Description
Experimental groups (white noise,ear plug and instrumental music) measuring quality and quantity of patients in the past in the first day of hospitalization . playing and using white noise (sound of ocean), ear plug and a music with no lyrics for 45 minutes at night. measuring sleeping quantity of patients every three day through Sleep Log sleep quantity index. measuring sleeping quality of patients at the end of day three through Petersburg sleep quality index.

Category
Treatment - Other

2

Description
control group, measuring the previous quantity and quality of patients' sleeping during last month through Petersburg sleeping quality index and sleeping quantity index (sleep log). Not recive disturbance for patients and recive rotin care during these three nights. Measuring sleeping quantity through sleeping quantity index (sleep log) during three days. Measuring sleeping quality through Petersburg sleeping quality index at the end of day three.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Mohammad Ali Cheraghi

Street address
Dr Garib St.

City
Tehran

2

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Mohammad Ali Cheraghi

Street address
Tehran- Shariati Hospital

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3

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Mohammad Ali Cheraghi

Street address
Tehran-Sina Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Masoud Younesian

Street address
Central Building, Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Khadijeh Akbari

Position
Master styudent of nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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PhD in Nursing (Associate Professor)

Other areas of specialty/work

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Person responsible for updating data

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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