

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

fatemeh_bahramnezhad@yahoo.com

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/s

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 receive disturbance for patients and receive routine 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

City

Tehran

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.

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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 student of nursing

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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PhD in Nursing (Associate Professor)

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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