Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of sensory restriction and music on sleep quality in patients with acute coronary syndrome in the cardiac care units 2012 .

Protocol summary

Summary

The purpose: Promoting the quality of sleep in coronary patients using eyelid, ear plug and music. 2) Design: 75 patients staying in CCU due to acute coronary are divided in to 3 groups: A) Control group. B) Eyelids & ear plugs group. C) Music group. 3) Direction: The patients get acquainted with the devices and get to know the purpose of the research, the morning after entering it. No special arrangements are taken in to consideration regarding the control group. In group B, eye lids &ear plugs are employed which are not removed until morning. In group C, music is employed. The head phones are removed when the patient falls asleep. The SMHSQ tests are given to the patients to answer in the morning. Entering criteria: Patients suffering from acute coronary syndrome who have spent at least 2 nights in the hospital and is not satisfied with his sleep in the ward. Excluding criteria: Major sleeping disorder, visual and auditory deficiency, sensory, neurological & psychological disorders, pulmonary edema, drug addiction, those in need of pain killers during the night due to severe pain. Primary outcome: the quality of sleep in patients with acute coronary syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515534N1**
Registration date: **2014-05-26, 1393/03/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

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Shiraz University of Medical Sciences.
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences.

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of sensory restriction and music on sleep quality in patients with acute coronary syndrome in the cardiac care units 2012 .

Public title

Comparing the effects of music and the use of eyelid and earplugs on the quality of sleep in coronary patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patient: Suffers from acute

coronary syndrome and is admitted in CCU; Has spent at least two nights in CCU; Is conscious and breathes spontaneously; Has no previous significant records of sleeping disorder; Does not suffer from auditory or visual disorders; Does not suffer from psychological or sensory-nervous disorders; Is not an addict; Has no records of advanced heart failure or pulmonary edema; Complains about his sleep in the ward. Exclusion criteria: The patient: Is disinclined to continue cooperating; Has spent less than three nights in CCU; Death or an increase in the level of consciousness occurs; Has received narcotics up to four hours before intervention; Did PCI or angiography in the evening of the same day or these procedures are scheduled to be done in the following day; Needs pain killers due to feeling pain during the night; Needs various procedures during the night.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **75**

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

1

Registry name
none

Secondary trial Id
none

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee.

Street address
Zand street, Shiraz

City
Shiraz

Postal code

Approval date
2013-03-06, 1391/12/16

Ethics committee reference number
91/429865

Health conditions studied

1

Description of health condition studied
Low sleep quality in patients with acute coronary syndrome.

ICD-10 code
G 47.0

ICD-10 code description
Disorders of initiating and maintaining sleep[insomnias].

Primary outcomes

1

Description
The quality of sleep in coronary patients with acute coronary syndrome.

Timepoint
At least at the second consecutive night spent in CCU and one night after that, in two consecutive nights.

Method of measurement
SMHSQ questionnaire; Sleep assessment visual scale; Comfort visual scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention: The eyelids and earplugs will be given to the patients in the morning of the night of the study and the questions concerning them will be answered. In order not to interrupt the sleep of the patients, the devices are not removed during the night. The eyelids are soft and anti-allergic and are so chosen in order not to make patients feel uncomfortable. The earplugs are made of silicon and in addition to being comfortable are soundproof.

Category
Rehabilitation

2

Description
No special arrangements are taken into consideration in the control group.

Category
Rehabilitation

3

Description
Second intervention: The patient listens to the music composed based upon the frequency of sleep and is a mixture of the sounds heard in the nature. The music is played through light headphones which are removed carefully after the patient falls sleep.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Azzahra Cardiac Hospital.

Full name of responsible person
Marzie Momennasab, PHD, Professor assistant.

Street address
Shishegari three way, Shiraz.

City
Shiraz.

2

Recruitment center

Name of recruitment center
Dr.Faghihi Hospital.

Full name of responsible person
Marzie Momennasab, PHD, Professor assistant.

Street address
Zand street, Shiraz.

City
Shiraz.

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences.

Full name of responsible person
Dr.Gholamreza Hatam.

Street address
Zand street, Shiraz.

City
Shiraz.

Grant name
91/429865

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Shiraz 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
Shiraz University of Medical Sciences.

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Marzie Momennasab.

Position
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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