Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of earplugs and eye masks during the night on the onset of delirium and sleep quality in patients undergoing coronary artery bypass grafting

Protocol summary

Study aim

Determining the effect of using earplugs and eye masks during the night on sleep quality and onset of delirium in patients with coronary artery bypass graft surgery.

Design

Single blind randomized controlled clinical trial with control group will be selected by block random sampling method on 114 eligible patients with coronary artery bypass graft surgery and will be placed in two experimental and control groups. Then the random arrangement of the samples will be done using Random Allocation Software 2.0 in the form of 19 blocks of 6.

Settings and conduct

The intervention is performed simultaneously with the use of eye masks and earplugs in the intensive care unit for three consecutive nights from 21-22 to 6-7 in the morning for the experimental group. Turn the earplug into a thin spiral by twisting it, and then pull the sponge into the ear canal by pulling the top of the ear up and back and hold it for 20-30 minutes so that the sponge expands in the ear canal. The control group receives only routine ward care.

Participants/Inclusion and exclusion criteria

Patients aged ≥18 years People who have undergone coronary artery bypass graft surgery Orientation to person, time and place absence of hearing, speech and vision impairment No previous cognitive pathology (including dementia, stroke, traumatic brain injury, encephalopathy, drug and alcohol abuse) no need for intubation more than 24 hours

Intervention groups

The intervention is performed simultaneously with the use ofearplugs and eye masks for three consecutive nights (from the second night of admission) from 21-22 to 6-7 in the morning by the care nurse for the experimental group. they receive.

Main outcome variables

Sleep quality and severity of delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051370N2**
Registration date: **2021-07-23, 1400/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-23, 1400/05/01**
Update count: **0**

Registration date

2021-07-23, 1400/05/01

Registrant information

Name

Seyed Afshin Shorofi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-22, 1400/04/31

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of earplugs and eye masks during the night on the onset of delirium and sleep quality in patients undergoing coronary artery bypass grafting

Public title
The effect of using eye masks and earplugs on the onset of postoperative confusion

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged ≥18 years People who have undergone coronary artery bypass graft surgery orientation to time, place and person absence of hearing, speech and vision impairment No previous cognitive pathology (including dementia, stroke, traumatic brain injury, encephalopathy, drug and alcohol abuse) no need for intubation more than 24 hours

Exclusion criteria:
Delirium at the time of entry criteria based on the Neecham scale

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be recruited using convenience sampling method and then will be randomly assigned to the experimental (group A) and control (group B) groups using block method (19 blocks) of length 6. The blocks will be numbered and sealed in 19 sequentially numbered opaque envelopes in random order (by someone outside the research team and unaware of the research objectives). The envelopes will be opened individually and the patients will be assigned to the relevant groups. The Random Allocation Software 2.0 will be used to generate randomization sequences.

Blinding (investigator's opinion)
Single blinded

Blinding description
the Assessor and Statistician will be blind to Randomization.

Placebo
Not used

Assignment
Parallel

Other design features
The experimental group will receive earplugs and eye masks And the control group receive only routine care. The intervention is performed simultaneously with the use of eye masks and earplugs in the cardiac intensive care unit for three consecutive nights (from the second night of admission) from 21-22 to 6-7 am by the caring nurse for the experimental group. Press and twist the earplugs into a spiral and thin, and then by pulling the top of the ear up and back, smooth the ear canal and press the sponge into the ear canal and hold 20-30 until the sponge expands in the ear canal. And after 10 minutes, check if the eye masks and earplugs are in place. If necessary, the patient's eye masks and earplug can be removed and reused to communicate with the patient and perform medical and nursing care. The earplugs is disposable, but the eye masks can be used for three nights of intervention.

Secondary Ids

1

Registry name
کمیته تخصصی اخلاق در پژوهش های زیست پزشکی

Secondary trial Id
IR.MAZUMS.REC.1400.303

Registration date
2021-07-07, 1400/04/16

Ethics committees

1

Ethics committee

Name of ethics committee
Bioethics Committee of Mazandaran University of Medical Sciences

Street address
Moalem Square, Sari, Mazandaran Province

City
sari

Province
Mazandaran

Postal code
4815733971

Approval date
2021-06-22, 1400/04/01

Ethics committee reference number
IR.MAZUMS.REC.1400.303

Health conditions studied

1

Description of health condition studied
delirium and sleep quality

ICD-10 code
F05

ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
delirium severity and sleep quality
Timepoint
Baseline (before intervention: T0); Follow-ups For three consecutive nights (from the second night of admission)
Method of measurement
Two Neelon-Champagne Confusion Scale and Verran and Snyder-Halpern Sleep Scale to evaluate delirium severity and sleep quality

Secondary outcomes

empty

Intervention groups

1

Description
The intervention is performed by using eye masks and earplugs from the second night after coronary artery bypass graft surgery for three consecutive nights (from the second night of admission) from 21-22 to 6-7 in the morning by the Caring nurse for the experimental group. paksaman eye masks (Model 504, made in Iran) made of a thin layer of foam covered by a layer of anti-allergy fabric and placed with a soft and light elastic around the head And the classic 3M sponge earplug with 33 dB sound reduction capability will be used.Press the earplug into a spiral and thin, and then by pulling the top of the ear up and back, smooth the ear canal and press the sponge into the ear canal and hold 20-30 until the sponge expands in the ear canal. And after 10 minutes, check if the blindfold eareplug and earmuffs are in place.If necessary, the patient's eye masks and earplug can be removed and reused to communicate with the patient and perform medical and nursing care. The eye mask is disposable, but the blindfold can be used for three nights of intervention.
Category
Prevention

2

Description
The control group also receives only routine ward care without any intervention.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital, Sari
Full name of responsible person
seyed afshin shorofi
Street address
Mazandaran, Sari, Imam Hossein Square, Army Boulevard, next to the Blood Transfusion Organization, Fatemeh Zahra Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Prof. Majid Saeedi
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Grant name
Mazandaran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Seyed Afshin Shorofi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable