

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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 of earplugs 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

ashorofi@yahoo.com

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

City

sari

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۳۳۱۱۱-۱۴۳۳۹

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+98 11 3332 3023

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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

Street address

sari, Moallem Square

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4817844718

Phone

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Email

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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

Ph.D.

Other areas of specialty/work

Nursery

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Imam square, Three-way Joibar, Mazandaran
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Contact**Name of organization / entity**

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Full name of responsible person

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Full name of responsible person

Dr Seyed Afshin Shorofi

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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