Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of two different methods of using earplugs versus control group on the pain intensity and sleep quality in patients undergoing coronary artery bypass graft: a randomized clinical trial

Protocol summary

Study aim
To compare the effect of two different methods of using earplugs versus control group on the pain intensity and sleep quality in patients undergoing coronary artery bypass graft

Design
This is a randomized clinical trial, phase II, in which 84 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients undergoing coronary artery bypass graft who will refer to Chamran Hospital in Isfahan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 65 to 90 years Indication of undergoing coronary artery bypass graft Ability to reading Exclusion criteria: Deafness Chronic sleep disorder Using hypnotic drugs Addiction to an opioid substance Psychiatric disorders Old hearing or using the hearing aid

Intervention groups
Intervention group 1: Using earplug in twice from 2 to 5 pm during the midday sleep from 10 to 6 pm during the night sleep Intervention group 2: Using earplug in once from 10 to 6 pm during the night sleep Control group: Without using any earplug

Main outcome variables
Primary outcome: Assessing the pain severity Assessing sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N291**
Registration date: **2019-09-05, 1398/06/14**
Registration timing: **prospective**

Last update: **2019-09-05, 1398/06/14**
Update count: **0**

Registration date
2019-09-05, 1398/06/14

Registrant information

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two different methods of

using earplugs versus control group on the pain intensity and sleep quality in patients undergoing coronary artery bypass graft: a randomized clinical trial

Public title
Comparison of the effect of two different methods of using earplugs versus control group on the pain intensity and sleep quality in patients undergoing coronary artery bypass graft

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 65 to 90 years Indication of undergoing coronary artery bypass graft Ability of read

Exclusion criteria:
Deafness Chronic sleep disorder Using hypnotic drugs Addiction to opioid substance Psychiatric disorders Old hearing or using hearing aid

Age
From **65 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare 84 sheets of paper, writing on 28 sheets the name of the intervention 1 and on 28 other sheets the name of the intervention 2 and on the third 28 sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn.

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
Ethics Committee of Isfahan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Isfahan University of Medical Sciences, Azadi Square, Hezarjarib Ave.

City
Hamadan

Province
Hamadan

Postal code
8174673465

Approval date
2019-08-18, 1398/05/27

Ethics committee reference number
IR. MUI.RESEARCH.REC.1398.293

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft

ICD-10 code
I25.729

ICD-10 code description
Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris

Primary outcomes

1

Description
Assessing the pain severity

Timepoint
On the first, second, and third days after surgery

Method of measurement
Using a visual analog scale (VAS)

2

Description
Assessing sleep quality

Timepoint
On the first, second, and third days after surgery

Method of measurement
Using Veran Snaider Halpern (VHS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Using earplug in twice from 2 to 5 pm during the midday sleep from 10 to 6 pm during the night sleep

Category
Treatment - Devices

2

Description
Intervention group 2:Using earplug in once from 10 to 6 pm during the night sleep
Category
Treatment - Devices

3

Description
Control group:Without using any earplug
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital in Isfahan City
Full name of responsible person
Fatemeh Bastani
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
8174673465
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfarayen 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
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available