

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

##### Street address

Chamran Hospital, Azadi Square, Hezarjarib Ave.

##### City

Isfahan

##### Province

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8174673465

##### Phone

+98 31 3792 7565

##### Email

f.bastani1971@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfarayen University of Medical Sciences

##### Full name of responsible person

Dr Shaghayegh Haghjooy Javanmard

##### Street address

Isfahan University of Medical Sciences, Azadi Square, Hezarjarib Ave.

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info.research@iums.ac.ir

##### 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

Esfarayen University of Medical Sciences

##### Full name of responsible person

Fatemeh Bastani

##### Position

Nursing Student

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Narges Kheirollahi

##### Position

PhD in Nursing

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Ph.D.

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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Hamadan

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6517838695  
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poorolajal@umsha.ac.ir

## 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