

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effects of listening to natural sound on pain intensity after Coronary artery bypass graft surgery.

#### Protocol summary

##### Study aim

The aim of this study is evaluating the effect of listening to natural sounds in reducing pain after coronary artery bypass graft

##### Design

Study is randomized single-blind parallel 2-arm clinical trial, designed on 92 patients undergo Coronary artery bypass graft to assessment severity of pain after listening natural sounds.

##### Settings and conduct

The randomized single blind clinical trial, conducted in open heart Intensive care unit Sina hospital. 92 patients who were scheduled to undergo Coronary artery bypass graft surgery were randomly allocated in two groups of 46. 1 group listened to their natural sound in two times (morning and afternoon), whereas the other group did not listen to natural sound. Using a visual analog Scale, pain intensity was measured before the intervention and 20 min after the intervention. Morphine dosage, need for inotropic and need for balloon pump and VAS numbers were compared between two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient desire for participating in study, non-emergency surgery, first experience of open heart surgery, stable hemodynamic SBP 90mmHg, no life-threatening dysthymia, HR 60-100, age more than 15y, non-addiction, no sedative medication addiction, no mental retardation, no hearing impairment. Exclusion criteria: using unusual analgesic interventions like massage therapy, delirium, any post-operation side effects, patients undesired for participation.

##### Intervention groups

Intervention group listened to their natural sound in two times (morning and afternoon), whereas the other group did not listen to natural sound. Using VAS, pain intensity was measured among the patients before the intervention and 20min after the intervention. Morphine dosage, need for inotropic and need for balloon pump and VAS were compared between two groups.

#### Main outcome variables

Visual analog scale, Balloon pump, morphine, inotropic

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220103053609N2**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **retrospective**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

##### Registration date

2022-09-28, 1401/07/06

##### Registrant information

##### Name

Mahsa Ghorbanzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2219 6207

##### Email address

mahsaghorbanzadeh1992@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-09, 1396/01/20

##### Expected recruitment end date

2018-02-09, 1396/11/20

##### Actual recruitment start date

2017-05-20, 1396/02/30

##### Actual recruitment end date

2018-02-19, 1396/11/30

**Trial completion date**

2018-04-30, 1397/02/10

**Scientific title**

The effects of listening to natural sound on pain intensity after Coronary artery bypass graft surgery.

**Public title**

The effect of music on pain reduction after Coronary artery bypass graft

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients who have the first Coronary artery bypass graft surgery experience

**Exclusion criteria:**

Using unusual analgesic methods

**Age**

From **15 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **92**

Actual sample size reached: **92**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this clinical trial study, 92 patients who were scheduled to undergo CABG surgery randomly will be included in the study. For random allocation of individuals in the study groups (intervention or intervention group and comparison or comparison group), the method of random allocation with block method (Block Randomization) will be used. In this method, blocks with size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1: 1 will be used. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified on the cards and these cards are placed inside the sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is single-blinded and blinding is done only on the analyzer that is unaware about two groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan Beheshti University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Approval date**

2022-09-13, 1401/06/22

**Ethics committee reference number**

IR.MUI.REC.1396.3.027. با سلام و عرض ادب کد اخلاق مطالعه ی IR.MUI.REC.1396.3.027. فوق در نامه ای که از جانب معاونت تحقیقات خطاب به دکتر سلیمانی ارسال شده بود ذکر شده بود و اینجانب نامه ی فوق را قبلا خدمتتان ایمیل کرده بودم و مجدد ایمیل میکنم. آیا باز هم نیاز به گرفتن گواهی می

**Health conditions studied****1****Description of health condition studied**

Coronary artery bypass graft

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease of native coronary artery

**Primary outcomes****1****Description**

Pain

**Timepoint**

Before and after intervention

**Method of measurement**

Visual analog scale questionnaire

**Secondary outcomes****1****Description**

Morphine dosage

**Timepoint**

Before and after intervention

**Method of measurement**

Patient's medical file

**2****Description**

Aortic Balloon pomp

**Timepoint**

Before and after intervention

**Method of measurement**

Patient's medical file

**3****Description**

Using inotropic medication

**Timepoint**

Before and after intervention

**Method of measurement**

Patient's medical file

**Intervention groups****1****Description**

Intervention group listened to their natural sound in two times (morning and afternoon). Using VAS, pain intensity was measured among the patients before the intervention and 20min after the intervention. Morphine dosage, need for inotropic and need for balloon pomp were measured.

**Category**

Rehabilitation

**2****Description**

Control group: patients without listening music before and 20min after in 2 times morning and afternoon, Morphine dosage, need for inotropic and need for balloon pomp and VAS were measured .

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina hospital

**Full name of responsible person**

Mahsa ghorbanzadeh

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Unit 5, No 10, eastern nazari alley, Sadaf St, western sarv St, Saadat Abad

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**Phone**

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**Email****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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Unit 5, No 10, eastern rose alley, Sadaf St, Weastern Sarv St, Saadatabad, Tehran, Iran

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahsa ghorbanzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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Resident  
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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All patient data can be shared through files after identifying them.

### When the data will become available and for how long

Access period 1 month after printing the results

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

### Under which criteria data/document could be used

Any use to help advance science is unrestricted.

### From where data/document is obtainable

Email address to mahsa ghorbanzadeh  
Mahsaghorbanzadeh92@gmail.com

### What processes are involved for a request to access data/document

After sending an email to request, they can access the information within a month.

### Comments