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-bilnded 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 pomp and VAS numbers were compared between two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patient desire for participating in study, nonemergency surgery, first experience of open heart surgery, stable hemodynamic SBP 90mmgh, 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 postoperation 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 pomp and VAS were compared between two groups.

Main outcome variables
Visual analog scale , Balloon pomp, 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
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Iran (Islamic Republic of)
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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 siza 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 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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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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