Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Music on Intensity of Postoperative Pain, Vital Sign and SPO2 in patients Undergoing Open heart surgery

Protocol summary

Summary

This study is a quasi-experimental, randomized clinical trial that will be done in the patients undergoing open heart surgery admitted in open heart ICU, affiliated to Mazandaran Medical Sciences University. Sixty eligible patients will be randomly divided into two groups. On the day before surgery, the patients in the intervention group will choose their favorite music. After the surgery and 24 hours after admission in ICU, pain intensity (using numerical rating scale and Face scale), heart and respiratory rate, blood pressure, SPO2 and mean arterial pressure (MAP) will be checked and then the patients will listen to their favorite music using Mp3 player & headphones for 30 minutes. The evaluation will be repeated immediately, 30 minutes, and 60 minutes later as well. The patients in control group receive no intervention unless wearing headphone. The measurements will be the same for two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903194133N1**
Registration date: **2010-05-10, 1389/02/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-10, 1389/02/20

Registrant information

Name

Amir Emami zeydi

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1322 0294

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-05-10, 1389/02/20

Expected recruitment end date

2010-08-11, 1389/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Music on Intensity of Postoperative Pain, Vital Sign and SPO2 in patients Undergoing Open heart surgery

Public title

Effect of Music on Intensity of Postoperative Pain, Vital Sign and SPO2 in patients Undergoing Open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent, non-emergency open heart surgery, no previous history of heart surgery and having stable hemodynamic status (systolic blood pressure greater than 90 mmHg, the lack of life threatening dysrhythmias and heart rate between 60 to 100 bpm Exclusion criteria: Need for mechanical ventilation on the time of study, history of psychiatric illness, history of chronic pain, hearing deficit, opiate

drug usage 4 hours before the intervention in the ICU, history of playing musical instruments and need to IABP (intraaortic ballon pump), any complication during anesthesia or surgery or the patients dissatisfaction to continuing the study

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Deputy of research of Mazandaran University of Medical Sciences

Street address
Deputy of research of Mazandaran University of medical sciences, Moalem Square, Sari

City
sari

Postal code

Approval date
2010-07-07, 1389/04/16

Ethics committee reference number
8957

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
Y83,Y84, R

ICD-10 code description
Surgical and other medical procedures as the cause of abnormal reaction of the patient, Acute pain

Primary outcomes

1

Description
Pain Intensity

Timepoint
Before the intervention, immediately after the intervention, 30 minutes after intervention, 60 minutes after intervention

Method of measurement
NRS (numerical rating scale) and Face scale

2

Description
Vital Sign

Timepoint
Before the intervention, immediately after the intervention, 30 minutes after intervention, 60 minutes after intervention

Method of measurement
Monitoring

3

Description
SPO2

Timepoint
Before the intervention, immediately after the intervention, 30 minutes after intervention, 60 minutes after intervention

Method of measurement
Monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Listening to preoperative patient-selected music, 24 hours after admission to ICU open heart, for 30 minutes through headphones

Category
Other

2

Description
For patients In the control group 24 hours after surgery only headphones without music for 30 minutes will be used

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran Heart Center
Full name of responsible person
Amir Emami Zeydi
Street address
Mazandaran Heart Center, Artesh Boulevard, Sari
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research of Mazandaran University of medical sciences
Full name of responsible person
Dr Ahmad Ali Enayati
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Deputy of research, Mazandaran university of medical sciences
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Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research of Mazandaran University of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty