

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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.

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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

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

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

Street address

Deputy of research, Mazandaran university of medical sciences

City

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

Contact

Name of organization / entity

Nasibe faculty of nursing and midwifery, sari, Iran

Full name of responsible person

Amir Emami Zeydi

Position

student of critical care nursing

Other areas of specialty/work

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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