Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial on the influence of sound therapy on signs variations of hemodynamic orthopedic patients.

Protocol summary

Summary

The goal of this study is examining the Influence of sound therapy on variations of hemodynamic in orthopedic patients during general anesthesia. In the operation day, during and after the beginning of general anesthesia, the patients' hemodynamic signs(blood pressure, heart beat) in both groups are recorded. Population under study, all people refering to Jahrom Peymanie Hospital will undergo orthopedic surgery by general anesthesia if they lack in criteria excluding them from study. Sample of 72 is estimated prior to operation, patients are put into two groups by tossing a coin:1. Observer2.sound therapy intervention. In the first group, after entering the operation room, the patients' hemodynamic signs will be recorded right away. however, in the second one, patients's hemodynamic signs are recorded by using headphones and playing sound. The night before operation day, the patients are visited and their information is completed. After operation and entrance to recovery, their hemodynamic signs are recorded every 5 minutes and this procedure lasts for 20 minutes. All patients must have cautious written consent to be allowed to participate in the study. The patients suffering the chronic and cancer-related pains, hearing and speech impairment and the lack of mental emotional health will be excluded from the study. It is expected that the intervention results in a reduction in the hemodynamic signs variations and an increase in the satisfaction of using the non drug method of pain control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051414049N5**
Registration date: **2017-10-05, 1396/07/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-10-05, 1396/07/13

Registrant information

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Name of organization / entity
Jahrom University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on the influence of sound therapy on signs variations of hemodynamic orthopedic patients.

Public title

the Influence of sound therapy on signs variations of hemodynamic in upper-body orthopedic patients during general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : All the patients who are to undergo anesthesia for upper body orthopedic operations in peymanie hospital connected with Jahrom medicine university.Cautious consent for participating in the study, is one of the main entrancecriteria.Exclusion criteria:Not interested in nature sounds, Those who are addict or has been using drugs and painkillers over a long time Those patients undergoing operation who need action or medications besides to routine care to get rid of side effects and pain relief.Unstable hemodynamic status, state results in chronic and cancer-related pains , Hearing or speech impairment, lack of mental emotional health and expressing disagreement for continuing the research.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study sampling process is carried out through tossing coin in order to divide them into two groups: Control group and Intervention group Double blind method has been used in this study so that the 1- The volunteer and 2- The person who records hemodynamic sign are not aware of measurement methods in intervention and control group. about the way people are put in intervention,control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Jahrom University of Medical Sciences

Street address

School of Nursing and Midwifery, Motahhari Blvd, Jahrom

City

Jahrom

Postal code

Approval date

2018-07-05, 1397/04/14

Ethics committee reference number

IR.JUMS.REC.1396.027

Health conditions studied

1

Description of health condition studied

hemodynamic changes after sound therapy

ICD-10 code

Z01.8

ICD-10 code description

Other specified special examinations

Primary outcomes

1

Description

Hemodynamic variations

Timepoint

Every 5 minutes over 20 minutes during anesthesia

Method of measurement

Every 5 minutes over 20 minutes during anesthesia

Secondary outcomes

1

Description

Agitation

Timepoint

when exiting the anesthesia

Method of measurement

Richmond scale

Intervention groups

1

Description

Intervention group: intervention includes using headphone and playing sound. by using headphone, comforting sound of nature such as birds, river, waterfall sounds will be played for each patients and then their hemodynamic signs will be recorded.

Category

Treatment - Other

2

Description

In the Control group after entering the operation, Hemodynamic signs would be recorded without any further action..

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Jahrom Peymanie Hospital

Full name of responsible person
Hojati Hamed Seyed

Street address
Jahrom، Jahad Square، Peymanie Hospital

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Jahrom University of Medical Sciences

Full name of responsible person
Solh Ju Kavos

Street address
Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

City
Jahrom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Jahrom 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
Jahrom University of Medical Sciences

Full name of responsible person
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Position
Anesthesia Undergraduate Student

Other areas of specialty/work

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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