Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of using sound frequencies on analgesia level and hemodynamic disorders during intubation and extubation in patients under general anesthesia

Protocol summary

Study aim

Determining the effects of using sound frequencies on the level of analgesia and hemodynamic disorders during intubation and extubation in patients under general anesthesia.

Design

The current study is a randomized double-blind clinical trial in phase 2 with a control group, which is conducted on 175 patients. The randomization of the samples is done using the order of random letters by computer software.

Settings and conduct

The study is conducted on elective candidates for general anesthesia in Imam Reza Hospital, Kermanshah. In the intervention groups, the application of different sound frequencies during the process of general anesthesia is done by headphones. The patients and the researcher who recorded the data do not know about the grouping and the type of intervention.

Participants/Inclusion and exclusion criteria

Patients who are under general anesthesia.

Intervention groups

In control group 1; patients do not receive any sound stimulation. In control group 2; passive wireless headphones are placed on both ears of the patient so that the ambient sound intensity is less than 5 dB and the patient does not receive any sound stimuli. In the intervention groups: sound stimulation with frequencies of 5, 10, 20, 50 and 100 Hz from the time of entering the operating room until the patient leaves the recovery room through wireless headphones, receives sound stimulation with a sound intensity of 50 dB.

Main outcome variables

Changes in blood pressure; change in heart rate ; pain level; comfort; anxiety

General information

Reason for update

This update is being made to clarify and complete the registered information regarding the conduct of the study and to improve the consistency of the trial record with the study protocol and the actual procedures used during the study. These updates do not change the overall nature of the intervention or the main objectives of the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240123060780N3**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2026-10-08, 1405/07/16**
Update count: **1**

Registration date

2024-06-08, 1403/03/19

Registrant information

Name
Rasoul Kavyannejad
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

2024-07-22, 1403/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of using sound frequencies on analgesia level and hemodynamic disorders during intubation and extubation in patients under general anesthesia

Public title

Effects of sound frequencies on analgesia and hemodynamic changes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not having a history of underlying diseases such as blood pressure, diabetes, heart and lung diseases Patients with American Society of Anesthesiology (ASA) classification 1 and 2 Airway grade 1 Not receiving premedication the night before and the morning of the operation having full normal hearing (25 dB hearing threshold) Having full consciousness

Exclusion criteria:

History of smoking and addiction Having an ear infection and anatomical abnormalities of the auditory system Non-cooperation of the patient

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **175**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of samples in this study is done by computer software.Due to the 7 groups, a random order of letters A, B, C, D, E, F, G is made in blocks with a random number of 7 letters. Each letter is a symbol of one of the study groups. Then these obtained blocks are placed in sealed envelopes. Before starting the study, one of the researchers opens one of the envelopes and finally the patient is placed in one of the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In Control Group 1, headphones were placed over the patient’s ears; however, the headphones had no audio function and contained openings over the ear area, allowing patients to hear environmental sounds naturally. In Control Group 2, intact but inactive headphones were placed over the patient’s ears, preventing the patients from hearing environmental sounds. In the intervention groups, intact headphones were used to deliver auditory stimulation at the specified frequencies. Because the headphones were visually identical and patients were unaware of their group allocation and the frequency of the auditory stimulation, patients were blinded to both group assignment and intervention frequency. An investigator involved in the project was responsible for administering anesthesia and managing the patients throughout the anesthetic period and was blinded to group allocation and stimulation frequency. Auditory stimulation was delivered through the headphones, with the stimulation frequency configured via the headphones’ Bluetooth connection. Another researcher responsible for recording the study variables was unaware of the patients’ group allocation and the frequency of auditory stimulation received and was blinded to both. Statistical analyses were performed after completion of data collection.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah, Iran

City

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Province

Kermanshah

Postal code

6715847141

Approval date

2024-01-30, 1402/11/10

Ethics committee reference number

IR.KUMS.REC.1403.102

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

2

Description of health condition studied

surgical pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Heart rate

Timepoint

It is measured immediately and at 1, 2, 3, 4, and 5 minutes after intubation and extubation.

Method of measurement

Using monitoring connected to the patient

2

Description

mean arterial pressure

Timepoint

It is measured immediately and at 1, 2, 3, 4, and 5 minutes after intubation and extubation.

Method of measurement

using a monitor connected to the patient.

3

Description

Anxiety

Timepoint

It is measured before induction of anesthesia.

Method of measurement

The visual analog scale

4

Description

comfort

Timepoint

It is measured before induction of anesthesia.

Method of measurement

The visual analog scale

5

Description

Pain

Timepoint

Before discharge from the recovery unit and at 1, 3, and 6 hours after surgery.

Method of measurement

The visual analog scale

6

Description

Systolic and diastolic blood pressure

Timepoint

Every 15 minutes during anesthesia and also before leaving the recovery room

Method of measurement

using a monitor connected to the patient

7

Description

Heart rate

Timepoint

Every 15 minutes during anesthesia and also before leaving the recovery room

Method of measurement

Using patient-connected monitoring

8

Description

Bispectral Index value during general anesthesia

Timepoint

Before induction of general anesthesia, after induction of general anesthesia, and at 15, 30, 45, and 60 minutes, as well as after extubation.

Method of measurement

Continuous monitoring using a bispectral index monitor with a disposable forehead sensor

Secondary outcomes

1

Description

The amount of narcotic drugs used for analgesia (morphin) in the recovery department

Timepoint

It is measured in the recovery section.

Method of measurement

In terms of milligrams of the drug injected by anesthesia personnel

Intervention groups

1

Description

Control 1 group: perforated wireless headphones are placed over both ears, and patients do not receive any auditory stimulus or stimulation intervention. The perforated headphones allow ambient sounds to remain audible.

Category

Placebo

2

Description

Control 2 group: passive wireless headphones are placed over both ears to reduce the intensity of ambient sound

to less than 5 dB, and patients in this group do not receive any sound stimuli.

Category

Placebo

3

Description

Intervention group: patients receive sound stimulation with a frequency of 5 Hz and sound intensity of 50 dB through wireless headphones.

Category

Treatment - Devices

4

Description

Intervention group: patients receive sound stimulation with a frequency of 10 Hz and sound intensity of 50 dB through wireless headphones.

Category

Treatment - Devices

5

Description

Intervention group: patients receive sound stimulation with a frequency of 20 Hz and sound intensity of 50 dB through wireless headphones.

Category

Treatment - Devices

6

Description

Intervention group: patients receive sound stimulation with a frequency of 50 Hz and sound intensity of 50 dB through wireless headphones.

Category

Treatment - Devices

7

Description

Intervention group: patients receive sound stimulation with a frequency of 100 Hz and sound intensity of 50 dB through wireless headphones.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

said mohamadi

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Imam Reza Hospital, Parastar boulevard, Sorkhalijeh, Kermanshah

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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

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Said mohamadi
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available