Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of binaural sound waves on the level of anxiety, pain and vital signs of patients undergoing elective surgery with regional anesthesia

Protocol summary

Study aim
The effect of binaural sound waves on the level of anxiety, pain and vital signs of patients undergoing elective surgery with regional anesthesia

Design
A double-blind, randomized, controlled clinical trial with binaural and favorite music on 150 patients. Controlled randomization http://www.randomization.com was used for randomization

Settings and conduct
This study is conducted in a double-blind manner, in 3 binaural groups, favorite music and control in patients undergoing elective surgery in Kausar Sanandaj Medical Training Center, where the main researcher performed the randomization and the Clinical researcher monitored anxiety and vital signs Without knowing the type of intervention. And then the obtained numbers are performed by a statistical consultant without the knowledge of intervention and control patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Elective surgeries, patient satisfaction, conscious patients, no history of epilepsy, patients over 18 years old, no heart dysrhythmias, non-pregnant female patients, no neurological and psychiatric disorders, no use of anti-anxiety drugs, no drug opioid addiction, no Alcohol consumption in the past 12 hours, healthy hearing, no ear infection, no patient agitation, no history of chronic pain, no uncontrollable anxiety in the patient. Exclusion criteria: Urgency of surgery, occurrence of any unstable and severe hemodynamic changes after hearing the sound, unwillingness of the patient to continue the research, blood pressure above 140/100, disturbance in surgery due to equipment and technique, prolongation of surgery more than usual, use of anti hypertensive drugs Pain and anxiety during surgery

Intervention groups
Favorite music group - binaural group - control group without music

Main outcome variables
The effect of music on anxiety, pain and vital signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210314050703N3**
Registration date: **2023-07-07, 1402/04/16**
Registration timing: **prospective**

Last update: **2023-07-07, 1402/04/16**
Update count: **0**

Registration date
2023-07-07, 1402/04/16

Registrant information

Name
Negin Ghadami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3324 8519

Email address
ghadaminegin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-11, 1402/04/20

Expected recruitment end date
2023-09-11, 1402/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of binaural sound waves on the level of anxiety, pain and vital signs of patients undergoing elective surgery with regional anesthesia

Public title
The effect of binaural sound waves on the level of anxiety, pain and vital signs of patients undergoing elective surgery with regional anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elective surgeries patient satisfaction conscious patients patients over 18 years old non-pregnant female patients healthy hearing

Exclusion criteria:
history of epilepsy uncontrollable anxiety in the patient history of chronic pain patient agitation ear infection use of anti-anxiety drugs drug r opioid addiction Alcohol consumption in the past 12 hours neurological and psychiatric disorders heart dysrhythmias

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 150 patients undergoing elective surgery with regional anesthesia referred to Kawsar Sanandaj Medical Training Center were selected by controlled random sampling and divided into three control and intervention groups, binaural music and favorite music. By entering information on the site http://www.randomization.com, the main organizer of the project assigns a number to each sample, considering that headphones are placed for each of the 3 groups of patients, and the music corresponding to the number is given to the patient. Another researcher evaluates the anxiety and vital signs before and after the intervention without knowing about the intervention, and the analyst is not aware of the patient's information given that the numbers are given.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is conducted in a double-blind way, so that 150 samples are divided into three equal groups of control and intervention of binaural music and favorite music. A number is assigned in each sample, considering that headphones are placed for each of the 3 groups of patients, the music corresponding to the number is given to the patient (the researcher does not know the results of the patient's assessment). and vital signs before and after (the researcher does not know which patient is the music group or the control) and the analyst does not know about the patient's information due to the fact that the numbers are given.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Approval date
2023-04-15, 1402/01/26

Ethics committee reference number
IR.MUK.REC.1402.001

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety level before and after the intervention

Timepoint
before intervention and 20 minutes after intervention and after surgery

Method of measurement
Spielberger anxiety questionnaire

2

Description
Pain level before and after the intervention
Timepoint
before intervention and 20 minutes after intervention and after surgery
Method of measurement
Numerical pain Rating Scale

Secondary outcomes

1

Description
The patient's vital signs levels
Timepoint
Every 5 minutes in the first half hour and then every 15 minutes until the end of the intervention and at the end of the measurement
Method of measurement
Cardiorespiratory monitoring of the company of Poindangan Rah Saadat, model b9

Intervention groups

1

Description
Intervention group: binaural music, binaural sound waves are special musical interventions that have recently received attention among neuro physiologists and doctors as a therapeutic tool when two tones with different frequencies are sent to the brain from each ear. An interference is created which is called binaural sound waves. The frequencies of tones should be less than 1000 to 1500 Hz. The difference in frequencies is the same as binaural sound waves, which should be less than 30 Hz. At first, the patient is placed in a quiet environment for 10 minutes in the preparation of the operating room. Then binaural sound wave music will be played with headphones from 15 minutes before the surgery until the end of the surgery. Vital signs and anxiety are measured for the patient before, during and after the intervention
Category
Treatment - Other

2

Description
Intervention group: favorite music based on the patient's favorite music style after 10 minutes of entering the preparation department in the operating room, is played with headphones for the patient from 15 minutes before the operation until the end of the operation.
Category
Treatment - Other

3

Description
Control group: No intervention, After 10 minutes of entering the preparation department in the operating room, headphones are played without any music for the patient from 15 minutes before the operation until the end of the operation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kawsar Sanandaj Medical Education Center
Full name of responsible person
Dr. Negin Ghadami
Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3322 9494
Email
ghadaminegin@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Afshin Abdolmaleki
Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3322 9494
Email
info@muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Negin Ghadami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3322 9494

Email
ghadaminegin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Negin Ghadami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3322 9494

Email
ghadaminegin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Negin Ghadami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Kurdistan University of Medical Sciences, Faculty of Medical, Pasdaran St.

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3322 9494

Email
ghadaminegin@gmail.com

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Only publishable information that does not conflict with the principles of ethics in clinical trial research and informed consent and does not contain personal information of individuals will be published

When the data will become available and for how long
Starting the access period 6 months after printing the results"

To whom data/document is available
Only the people of the research team based on the principles specified in the research and the patients will be allowed to access their information at the specified

level. Other researchers and people will have access without mentioning the details of the analyzed information

Under which criteria data/document could be used

The ethics committee and legal authorities have the ability to access information according to the laws without mentioning the personal characteristics of individuals upon official request

From where data/document is obtainable

To access publishable information, you can refer to the research system of Kurdistan University of Medical Sciences at http://rms.muk.ac.ir

What processes are involved for a request to access data/document

Access to the documents is after obtaining permission from the Research Vice-Chancellor of Kurdistan University of Medical Sciences with the coordination of the main researcher of the research

Comments