

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigation the effectiveness and non effectiveness of Bainural Beat music to reduce anxiety and pain and increase the satisfaction of patients with eye surgery

Protocol summary

Study aim

Investigating the effectiveness of Binaural Beat music on reducing anxiety and pain and increasing the satisfaction of patients with eye surgery

Design

In this study, 60 patients who will referred to Imam Khomeini hospital and are eligible to enter the study will be selected conveniently. Participants will be divided into two groups and each participant will be given a code.

Settings and conduct

This study will be done non blinded in Imam Khomeini Hospital in Kermanshah city. Eligible patients, after entering the operating room will be connected to the monitoring by anesthetizing technician and prepared for desired surgery with anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of eye surgery; the absence of dangerous dysrhythms and heart rate between 60 and 100 beats per minute. Exclusion criteria: pregnant women; the occurrence of any complications during surgery and anesthesia.

Intervention groups

The intervention group will receive 1 µg of opiate plus Binaural music from the 5 minutes before the surgery until the end of the operation. The control group will receive one microgram of opiate from the 5 minutes before the start of the operation until the end of the operation

Main outcome variables

Anxiety; rate of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N89**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **retrospective**

Last update: **2018-04-02, 1397/01/13**

Update count: **0**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness and non effectiveness of Bainural Beat music to reduce anxiety and pain and increase the satisfaction of patients with eye surgery

Public title

Investigation the effectiveness of Bainural Beat music to reduce anxiety and pain and increase the satisfaction of patients with eye surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of eye surgery Hemodynamic stability (systolic blood pressure greater than 90 mmHg and less than 140 mmHg) The absence of dangerous dysrhythms and heart rate between 60 and 100 beats per minute

Exclusion criteria:

History of neurological diseases or spatial scarring Seizure A history of mental illness Pregnant women Drug use The occurrence of any complications during surgery and anesthesia

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-01-17, 1396/10/27

Ethics committee reference number

IR.KUMS.REC.1396.573

Health conditions studied

1

Description of health condition studied

preoperative anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after surgery

Method of measurement

Based on State-Trait Anxiety Inventory (STAI)

2

Description

Rate of pain

Timepoint

Before and after surgery

Method of measurement

VAS Scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 1 µg of opiate plus Binaural music from the 5 minutes before the surgery until the end of the operation.

Category

Treatment - Other

2

Description

The control group will receive one microgram of opiate from the 5 minutes before the start of the operation until the end of the operation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Amin Jalilian
Street address
Street Naghliyah
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
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Vice chancellor for research of Kermanshah University of Medical Sciences
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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
Private
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
Amin Jalilian
Position
Anesthesiology residents
Latest degree
Medical doctor
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)**

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

En In a 20-day period, the documents will be sent e-mail

Comments