

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+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

Street address

Vice chancellor for research of Kermanshah University of Medical Sciences

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fnajafi@kums.ac.ir

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

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Bahman Roshani

Position

Faculty Member of Medical University

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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

Anesthesiology

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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