Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effectiveness of listening to classical music during general anesthesia compared to white noise in reducing propofol consumption during vitrectomy surgery

Protocol summary

Study aim
Evaluating and comparing the impact of classical music on the consumption of propofol during vitrectomy surgery

Design
A clinical trial with a control group with parallel groups, double-blind, randomized using a random numbers table, in two groups of 25 people.

Settings and conduct
After obtaining consent, the study will involve all adults over the age of 18 who undergo vitrectomy surgery at Imam Hossein hospital in Tehran. A headset is put on the patient after general anesthesia. During the patient's admission into the operating room, an anesthesia technician randomly chooses the patient's group and plays the audio file corresponding to that group for the patient (intervention group, classical music file; control group, white noise file). The anesthesiologist in charge of the patient will record the variables assessed during and after the procedure in the questionnaire. No one will be informed of the patient's group except the first technician until the questionnaire is finished and the patient exits the operating room.

Participants/Inclusion and exclusion criteria
After obtaining informed consent from the patients, all patients over 18 years of age referred to the operating room for vitrectomy surgery will be examined. Patients with hearing impairment, mental health problems, long-term use of sedatives or painkillers, and people with alcohol addiction or other illegal drugs will be excluded from the study.

Intervention groups
Classical music will be used in the intervention group and white noise will be used in the control group (a type of sound that is created by combining sounds with different frequencies and is used as a control group in various music therapy studies).

Main outcome variables
Propofol dosage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120910010800N6**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **prospective**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

Registration date
2022-10-02, 1401/07/10

Registrant information

Name
Dariush Abtahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2263 2611

Email address
d.abtahi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-07, 1401/07/15

Expected recruitment end date
2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of listening to classical music during general anesthesia compared to white noise in reducing propofol consumption during vitrectomy surgery

Public title

Effect of music during general anesthesia on propofol consumption during vitrectomy surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

American Society of Anesthesiologists (ASA) Physical Status Classification System I and II vitrectomy surgery Age above 18 years Consent to study

Exclusion criteria:

hearing impairment mental health problem prolonged use of sedatives or analgesics alcoholism or other illicit drug addiction

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two intervention and control groups using six blocks of four in permutation blocks, and this process will be continued until all research participants have been enrolled. When the patient enters the operating room, the anesthesia technician performs this task and plays the audio player file that corresponds to the patient's group. Until the patient exits the operating room, the patient group won't be identifiable to anybody else.

Blinding (investigator's opinion)

Double blinded

Blinding description

Before performing anesthesia, an anesthesiologist will select the patient group using colored cards without the knowledge of the anesthesiologist, surgeon, and patient. After the induction of general anesthesia, headphones will be placed on the patient and the same technician will play the appropriate file for the group. The sound played for the patient will be at a level that cannot be heard by others. The headphones remain in place until the end of the surgery, and when the patient wakes up, the sound is stopped and then the headphones are removed. Until the questionnaire information is completed and the patient is removed from the operating room, no one except the technician will be aware of the patient's group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Science

Street address

Emam Hossein Hospital, Shahid Madani St.

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.286

Health conditions studied

1

Description of health condition studied

Vitrectomy Surgery

ICD-10 code

Z98.89

ICD-10 code description

Other specified postprocedural states

Primary outcomes

1

Description

Propofol consumption level

Timepoint

End of surgery

Method of measurement

A standard anesthesia sheet is used in the patient file to determine the total amount of propofol used in mg. The patient's propofol consumption at the beginning of anesthesia and then it is recorded in the file as standard and at the end the total amount is added together.

Secondary outcomes

1

Description
Post-operative nausea and vomiting
Timepoint
In recovery room
Method of measurement
Questionnaire

2

Description
Blood pressure
Timepoint
During and after the surgery
Method of measurement
Monitoring device

3

Description
Heart rate
Timepoint
During and after the surgery
Method of measurement
Monitoring device

4

Description
Bispectral index
Timepoint
During surgery
Method of measurement
Bispectral index device

5

Description
Pain
Timepoint
After surgery
Method of measurement
Using visual analog scale

Intervention groups

1

Description
Intervention group: After general anesthesia, a headphone is placed on the patient and the classical music file is played through it. The loudness of the sound is checked in advance using a sound sample for the comfort of the patient and is set below 85 dB (to prevent ear damage) based on the recommendation of the World Health Organization. The headphones remain in place until the end of the surgery. When the patient starts to wake up, the sound is stopped and the headphones are removed.
Category
Treatment - Other

2

Description
Control group: the white noise file is played for the patient. White noise is a type of sound that is created by combining sounds with different frequencies. If you combine all the imaginable sounds that a human can hear, white noise will be created. The adjective white has been chosen to describe this type of sound for the same reason that it is used to describe white light. Various studies use this sound to compare groups under music therapy as a control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Emam Hossein
Full name of responsible person
Dariush Abtahi
Street address
Shahid Madani St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshhin Zarghi
Street address
Tehran Province, Tehran, Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9770
Email

Intl_office@sbmu.ac.ir

Web page address

https://en.sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dariush Abtahi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how

long

One year after the publication of the article

To whom data/document is available

All jobs

Under which criteria data/document could be used

All non-personal patient information (anonymously) can be accessed by contacting the responsible author.

From where data/document is obtainable

email to: drdariushabtahi@yahoo.com

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

Sending email and review by the responsible author.

Comments