

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of lavender inhalation and nature sounds on anxiety, hemodynamic parameters and pain in patients undergoing cataract surgery with regional anesthesia

Protocol summary

Study aim

Determining the effect of lavender inhalation and nature sounds on anxiety, hemodynamic indices and pain of patients undergoing cataract surgery under regional anesthesia in the hospitals of Guilan University of Medical Sciences in 1401-1400

Design

120 patients, parallel clinical trial Online software (<https://www.randomizer.org/>) will be used and the code O for lavender, the code A for the sound group and the code C for the control group will be placed in the envelope. In this method, 120 packets will be packed. On the outside of each envelope is written a number from 1 to 120. At the time of the patient's visit, it will be opened and based on the code inside the envelope and the list of numbers obtained by the software, in which the order of patients' visits and the code is set, the patient will be divided into one of three groups.

Settings and conduct

Preoperative and postoperative eye surgery wards and intraoperative operating rooms. We evaluate the patient's anxiety in the ward with the Spielberger questionnaire in the inhaled lavender group and in the voice and control group. In the operating room, the hemodynamic status is monitored. Finally, the VAS scale is used to assess patients' pain 90 minutes after anesthesia.

Participants/Inclusion and exclusion criteria

Physical and mental ability to answer questions, willingness to participate in research, having informed satisfaction, full awareness of place, time and surroundings. Exclusion criteria: having a history of plant allergies, having olfactory disorders, unwillingness of the patient to Listening to music and not communicating verbally, taking anti-anxiety medication, history of eye surgery

Intervention groups

Lavender group, nature of sound, control

Main outcome variables

Anxiety; Hemodynamic changes and side effects including pain, SPO2 and various possible complications such as nausea and vomiting and abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210927052608N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

reza pourmohammad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-06-18, 1401/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavender inhalation and nature sounds on anxiety, hemodynamic parameters and pain in patients undergoing cataract surgery with regional anesthesia

Public title

Comparison of the effect of lavender inhalation and nature sounds on anxiety, hemodynamic parameters and pain in patients undergoing cataract surgery with regional anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with cataracts physical and mental ability to answer questions willingness to participate in research having conscious satisfaction full awareness of place, time and surroundings able to understand and speak Persian

Exclusion criteria:

Having a history of allergies to plants Having olfactory disorders The patient's unwillingness to listen to music Lack of verbal communication Taking anti-anxiety medication History of eye surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

A total of 120 eligible patients were selected continuously and after obtaining written consent, they will be randomly divided into three intervention groups with lavender, Voice of Nature and Control. For random assignment of samples in three groups, online software (<https://www.randomizer.org/>) will be used, code O for lavender, code A for the sound group and code C. For the control group, 120 envelopes are placed inside the envelope. In this method, 120 envelopes are written, and a number from 1 to 120 is written on the outside of each envelope. At the time of the patient's visit, it will be opened and based on the code inside the envelope and the list of numbers obtained by the software, in which the order of patients' visits and the code is set, the patient will be divided into one of three groups.

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 Mazandaran University of Medical Sciences

Street address

Sari, Moallem Square, Deputy of Research and Technology

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2022-04-13, 1401/01/24

Ethics committee reference number

IR.MAZUMS.REC.1401.048

Health conditions studied**1****Description of health condition studied**

patients undergoing cataract surgery with regional anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The primary outcome in this study was anxiety and hemodynamic changes

Timepoint

Before surgery, during surgery and 90 minutes after anesthesia

Method of measurement

To collect data, demographic information and disease information questionnaire, Spielberger manifest anxiety level questionnaire, hemodynamic index registration form and VAS scale for pain are used.

Secondary outcomes

1

Description

Secondary consequences include pain, SPO2, and various possible complications such as nausea and vomiting and abdominal pain, headache, and other satisfaction.

Timepoint

Before surgery, during surgery and 90 minutes after anesthesia

Method of measurement

. To collect data, demographic information and disease information questionnaire, Spielberger manifest anxiety level questionnaire, hemodynamic index registration form and VAS scale for pain are used.

Intervention groups

1

Description

Patients in the intervention group with lavender, two drops of Alice lavender essential oil are instilled on a cotton ball and placed with a pin on the collar of the patient's clothing or near the patient's pillow, and the patient is asked to stand normally for 15 minutes To breathe.

Category

Prevention

2

Description

Another intervention group is the nature of sound , which includes a combination of beach sounds, birds and rain. Wireless headphones are used to play music. Headphones can mask the sounds of the environment, so it makes the effect of the intervention clearer. The duration of playing the snature of sound, according to previous studies, is 15 minutes. The volume of nature's voice is adjusted by asking patients questions so that all patients receive a clear voice.

Category

Prevention

3

Description

Control group: do not receive any Lavender and nature of sounds.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Mo'menin Educational Remedial & Research Center

Full name of responsible person

reza pourmohammad

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17 Shahrivar St., behind the courthouse

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram ebrahimnejad

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Reza Pourmohammad

Position

MSC surgical technology

Latest degree

Master

Other areas of specialty/work

Surgical technologist

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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