Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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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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Latest degree

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Other areas of specialty/work

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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