Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of progressive muscle relaxation technique and inhalation aromatherapy with Lavender essence on anxiety and vital signs in patients undergoing spinal anesthesia

Protocol summary

Study aim
Comparison of progressive muscle relaxation technique and inhalation aromatherapy with Lavender essence on anxiety and vital signs in patients undergoing spinal anesthesia

Design
Clinical trial with a control group, with parallel groups, double blinded, randomized, on 123 patients. Permutation blocks were used for randomization.

Settings and conduct
Sampling will be performed in the operation room of Valiasr Hospital in Arak. The study conducted using Purposive Sampling method and patients randomly allocated into 3 different groups. This study is double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged over 18 years and under 65 years; negative history of known mental illness; negative history of allergies or respiratory diseases; negative history of using anxiolytics, opioids, or strong analgesics. Exclusion criteria: reluctant to continue study ,allergic to lavender essence inhalation, prone position

Intervention groups
In the progressive muscle relaxation group, patients are asked to contract their muscles from the plantar to the facial muscles and then relax. At the same time, patients will breathe deeply. In the aromatherapy group, 2 drops of 2% lavender essence is inhaled 20 minutes before spinal anesthesia. Patients in the control group will receive routine care during this time, and only research tools will be filled in by them

Main outcome variables
Anxiety,Vital signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180107038251N6**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date
2022-03-04, 1400/12/13

Registrant information

Name
Nazanin Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3366 1308

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-05, 1400/11/16

Expected recruitment end date
2022-10-08, 1401/07/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of progressive muscle relaxation technique

and inhalation aromatherapy with Lavender essence on anxiety and vital signs in patients undergoing spinal anesthesia

Public title
Comparison of progressive muscle relaxation technique and inhalation aromatherapy with Lavender essence on anxiety and vital signs
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Alertness and ability to speak Patients aged over 18 years and under 65 years. Negative history of known mental illness Negative history of allergies or respiratory diseases Negative history of using anxiolytics, opioids, or strong analgesics Absence of severe pain due to underlying disease(cancer) No contraindications for frequent muscle contractions and expansions Ability to read, write and understand Persian
Exclusion criteria:
Sudden pain not related to surgery Convulsion and any life-threatening emergencies History of mental illness being allergic to lavender inhalation Treatment with anti-depressants drugs Patients with cognitive, visual, or speech impairments Patients undergoing oncology surgery and major surgery Opioid, anti-anxiety drugs, muscle relaxants or any interfering drug requirement during spinal anesthesia Patients undergoing pilonidal sinus surgery or any surgery Which requires a prone position
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be selected by convenient sampling methods and then randomly assigned to intervention with aroma A ,massage B, and control C groups by permutation blocks with six blocks ABCABC,AABBCC,AACCBB,CCABAB.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will be divided into three groups: intervention 1, intervention 2, and the control group. One group is called A and the other groups are called B and C. Before and after the intervention, information is collected by the outcome assessor who is unaware of the classification. Data analysis is also performed by a person who is unaware of groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Railroad Street, Alamol Huda Street
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2021-12-05, 1400/09/14
Ethics committee reference number
IR.ARAKMU.REC.1400.256

Health conditions studied

1

Description of health condition studied
Anxiety in patients undergoing Spinal anesthesia
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Anxiety
Timepoint
30 minutes before spinal anesthesia and after surgery
Method of measurement
Spielberger Standard Questionnaire

2

Description
Respiratory rate
Timepoint
30 minutes before spinal anesthesia and after surgery
Method of measurement
Chest observation

3

Description
Pulse rate
Timepoint
30 minutes before spinal anesthesia and after surgery
Method of measurement
Pulse oximetry

4

Description
Temperature
Timepoint
30 minutes before spinal anesthesia and after surgery
Method of measurement
Thermometer

5

Description
Blood pressure
Timepoint
30 minutes before spinal anesthesia and after surgery
Method of measurement
Blood pressure monitor

Secondary outcomes

1

Description
Satisfaction level
Timepoint
From the beginning of anesthesia to the end of surgery
Method of measurement
5-point Likert scale 5-point Likert scale

Intervention groups

1

Description
Intervention group: In progressive muscle relaxation technique group, 30 minutes before spinal anesthesia the patient's vital signs will be monitored and the demographic and Spielberger questionnaires will be filled in, then, patients will be asked to first contract the muscles of the feet to the muscles of the face and then relax. At the same time, patients will breathe deeply during relaxation. The selected position for gradual relaxation will be lying down. after surgery, the vital signs will be checked and the Spielberger question will be filled in.
Category
Prevention

2

Description
Intervention group: 30 minutes before spinal anesthesia, the patient's vital signs will be monitored and recorded and the demographic questionnaire and Spielberger questionnaire will be filled in, then the pads saturated with 2 drops of 2% lavender essence, produced in Baricha Essence of Kashan Company, will be attached to the front of the chest. It will be inhaled for 20 minutes. Then, after surgery, the vital signs will be checked and the Spielberger question will be filled in.
Category
Prevention

3

Description
Control group: Patients in the control group will receive routine care during this period and only research tools will be filled in by them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr education and treatment center
Full name of responsible person
Nazanin Amini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Nazanin
Position
Academic Member
Latest degree
Master
Other areas of specialty/work
Anesthesiology
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سردشت، دانشگاه علوم پزشکی اراک، دانشکده پیراپزشکی
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available