

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)

Phone

+98 86 3366 1308

Email address

nazaninamini69@yahoo.com

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,AACBBB,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

Street address

Valiasr education and treatment center, Valiasr square

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3507

Email

nazaninamini69@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mr.Babaie

Street address

Arak University of Medical Sciences, Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3506

Email

pajooresh@arakmu.ac.ir

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
Street address
سردشت، دانشگاه علوم پزشکی اراک، دانشکده پیراپزشکی
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3507
Email
nazaninamini69@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Hessamedin Modir
Position
Academic member, Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address

Arak University of Medical Sciences, Sardasht
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3507
Email
modir.he@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Nazanin Amini
Position
عضو هیات علمی
Latest degree
Master
Other areas of specialty/work
Anesthesiology
Street address
Faculty of Paramedicine, Arak University of Medical Sciences, Sardasht
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3507
Email
nazaninamini69@yahoo.com

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