Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of aromatherapy with lavender and rose essential oil on pain score, anxiety score and physiological indicators in patients undergoing coronary catheterization through the radial artery: A Randomized Controlled Trial

Protocol summary

Study aim
Comparison of the effect of aromatherapy with lavender and rose essential oil on pain score, anxiety score and physiological indicators in patients undergoing coronary catheterization through the radial artery

Design
A clinical trial with two intervention groups and one control group, without blinding, included 123 patients with random allocation, for randomization process, R package software was used.

Settings and conduct
Patients who are elective candidates for coronary catheterization through the radial artery refferred to Shahid Boroujerdi Heart Surgery Center at Towhid Hospital in Sanandaj city, Kurdestan province

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Candidates for elective coronary catheterization via the radial artery Exclusion Criteria: Allergy to any of the essences used in the study, Unwillingness to continue cooperation, Any change in participant's clinical condition

Intervention groups
Patients will be randomly assigned to one of three groups: lavender, Damask rose aromatherapy, or control. Anxiety scores will be recorded in all three groups before the intervention. 20 minutes before arterial sheath removal, in addition to receiving routine care, patients in intervention groups A and B will receive sterile gauze impregnated with 5 drops of lavender essence or 5 drops of Damask rose essence, respectively. The gauze will be placed on the patient’s chest by the evaluator. In the control group, sterile gauze impregnated with 5 drops of distilled water will be used. After the intervention, physiological indicators and pain scores will be measured and recorded in all three groups during and at 10, 20, and 30 minutes after arterial sheath removal. Anxiety scores will also be assessed in all three groups before and 30 minutes after arterial sheath removal.

Main outcome variables
Pain score, Anxiety score, Physiological indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260511069351N1**
Registration date: **2026-06-04, 1405/03/14**
Registration timing: **prospective**

Last update: **2026-06-04, 1405/03/14**
Update count: **0**

Registration date
2026-06-04, 1405/03/14

Registrant information

Name
Seyedeh Boshra Sheikhahmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3362 9291

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boshra.sh1377@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-06, 1405/04/15

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy with lavender and rose essential oil on pain score, anxiety score and physiological indicators in patients undergoing coronary catheterization through the radial artery: A Randomized Controlled Trial

Public title

Comparison of the effect of aromatherapy with lavender and rose essential oil on pain score, anxiety score and physiological indicators in patients undergoing coronary catheterization through the radial artery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate selection via coronary catheterization through the radial artery Filling out the informed consent form voluntarily Age over 18 years Ability to read and write (literacy) Awareness of the time, place, and person

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization Method The method will be accessible. Block randomization will be performed to allocate 123 patients into three groups (41 individuals per group: A, B, C). This method ensures group balance and eliminates allocation prediction. Calculation of block size and number of blocks Block size: 6 individuals (2 per group; small block; multiplier of 3 for complete balance) Number of blocks: total sample size (123) divided by block size (6) equals 20 full blocks (120 individuals) + 1 incomplete block (2 individuals) (each block includes balanced random combinations such as AAB, BCC, or ABC). Blocks will be generated using the R software package (blockrand) and placed in sealed envelopes in Excel. The allocation will be performed independently and blindly. Block selection for intervention will be random. To prevent interference from routine effects, weekly interventions will be carried out. For example, block (ABC) includes three interventions: A intervention and C control in the first week, B intervention in the second week, and C group in the third week. After the third week, the second block will be randomly selected, following the same procedure until the sample size reaches 41 individuals per block.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gerash University of Medical Sciences

Street address

Imam Hossein (AS) Blvd, Daneshjoo Blvd, Gerash University of Medical Sciences

City

Gerash

Province

Fars

Postal code

7441758666

Approval date

2026-04-07, 1405/01/18

Ethics committee reference number

IR.GERUMS.REC.1405.003

Health conditions studied

1

Description of health condition studied

the effect of aromatherapy with lavender and rose essential oil on pain score, anxiety score and physiological indicators in patients undergoing coronary catheterization through the radial artery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain score

Timepoint

Before, during, 10, 20, 30 minutes after arterial sheath removal

Method of measurement

Visual Analogue Scale

2

Description
Anxiety score
Timepoint
Before the intervention, before and 30 minutes after arterial sheath removal
Method of measurement
Spielberger State Anxiety Inventory

3

Description
physiological indicators (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, respiratory rate and arterial blood oxygen saturation percentage)
Timepoint
Before, during, 10, 20, 30 minutes after arterial sheath removal
Method of measurement
Pouyandegan Rah Saadat company's Vital signs monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
The first Intervention group: inhaled 5 drops of pure lavender essential oil produced by Barij Essence Pharmaceutical Company, Kashan, for 20 minutes
Category
Treatment - Other

2

Description
The second Intervention group: inhaled 5 drops of pure rose essential oil produced by Barij Essence Pharmaceutical Company, Kashan, for 20 minutes
Category
Treatment - Other

3

Description
Control group: inhaled 5 drops of distilled water for 20 minutes
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Boroujerdi Heart Surgery Center, Towhid Hospital
Full name of responsible person
امید محمدی
Street address
Geryashan street, Towhid Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gerash University of Medical Sciences
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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
Gerash 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
Gerash University of Medical Sciences
Full name of responsible person

Seyyedeh Boshra Sheikhahmadi
Position
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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
No further information is available
Study Protocol
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
The full study protocol and final clinical trial report will be available through the IRCT website after publication of the study results and, if applicable, through the journal publishing the study findings. All participant identifiers will be removed to ensure confidentiality.
When the data will become available and for how long
The study protocol will be available after final registration, and the final study report will be available after publication of the results for at least 5 years.
To whom data/document is available
Researchers, academic staff, students, and other interested individuals may access the published study protocol and final study report.
Under which criteria data/document could be used
The shared documents may be used for research, educational, and scientific purposes only. Proper citation of the source is required, and participant confidentiality must be maintained.
From where data/document is obtainable
Requests for access may be submitted through the IRCT website or by contacting the principal investigator of the study.
What processes are involved for a request to access data/document
Requests will be reviewed by the principal investigator within 14 days. If approved, the requests documents will be provided within 7 days.
Comments