Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Inhalation Aromatherapy with Lemon Essence on Nausea, Vomiting, Pain, and Delirium in Patients Undergoing Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim
Determining the Effect of Inhalation Aromatherapy with Lemon Essence on Nausea, Vomiting, Pain, and Delirium in Patients Undergoing Coronary Artery Bypass Graft Surgery.

Design
A randomized, controlled clinical trial with two parallel groups, triple-blind, phase 3, and a sample size of 104 participants. Block randomization with blocks of four will be performed using Excel software.

Settings and conduct
This phase III randomized triple-blind trial with 104 participants will be conducted at Baghiatallah medical centers to evaluate lemon aromatherapy's effect on nausea, pain, and delirium after coronary bypass surgery. The intervention runs from the night before surgery to 24 hours after. Data will be collected via standard tools. Block randomization (blocks of four) and blinding of participants, researchers, assessors, and analysts will be used. Oils are coded by a third party.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 40–80 years, ASA class II or III, alert, without history of delirium or psychiatric disorders, no prior participation in similar studies, and scheduled for coronary artery bypass graft surgery. Exclusion Criteria: History of allergy to herbal products, presence of olfactory dysfunction

Intervention groups
Intervention group: Five drops of 100% lemon essential oil (produced by Barij Essence Company) on cotton, placed 10 cm from the nose, administered every 4 hours from the night before surgery until 24 hours after, by a trained nurse blinded to group allocation. Control group: Five drops of odorless bitter almond essential oil (Barij Essence), with identical packaging, method of administration, intervals, and frequency, applied every 4 hours.

Main outcome variables
Nausea and Vomiting, Pain, and Delirium after Coronary Artery Bypass Graft Surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231021059799N2**
Registration date: **2025-06-17, 1404/03/27**
Registration timing: **prospective**

Last update: **2025-06-17, 1404/03/27**
Update count: **0**

Registration date
2025-06-17, 1404/03/27

Registrant information

Name
Siavash Sangi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3823 5954

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siavashsangi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-11-06, 1404/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Inhalation Aromatherapy with Lemon Essence on Nausea, Vomiting, Pain, and Delirium in Patients Undergoing Coronary Artery Bypass Graft Surgery

Public title
The effect of aromatherapy with lemon essence on nausea, vomiting, pain, and delirium after heart surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 40 and 80 years Scheduled for coronary artery bypass graft surgery. ASA physical status class II and III. Patient is alert and oriented to time, place, and person, and able to speak No participation in other studies involving similar interventions. No history of postoperative delirium No diagnosis of known psychiatric disorders (e.g., severe depression, anxiety, psychosis, etc.) No history of alcohol use or antipsychotic drug consumption
Exclusion criteria:
History of allergy related to herbal extracts. Presence of olfactory dysfunction or structural nasal damage. History of reoperation following cardiac surgery. Anticipated prolonged surgery duration beyond standard limits, as assessed by the cardiac surgeon. History of receiving higher-than-usual doses of opioid medications in the cardiac intensive care unit. High risk of severe postoperative bleeding as predicted by the clinical care team.
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization with blocks of four will be used. Random sequences will be generated using Microsoft Excel and its random function. Each allocation within the randomization sequence will receive a unique numerical code, and participants will be randomly assigned to either the intervention or control group. The treatment regimen corresponding to each random sequence will be placed in sealed envelopes labeled with the assigned code. These envelopes will then be placed in a box in random order. The assigned codes and corresponding treatment types will be recorded and maintained by the study epidemiologist, who will retain access to the randomization list.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, triple-blinding will be implemented, meaning that the participants, the study investigator, the outcome assessor, and the data analyst will all remain unaware of the assigned intervention (aromatherapy with lemon essential oil or placebo). Given the distinctive scent of lemon essential oil, specific measures will be taken to maintain participant blinding. Upon enrollment, participants will be informed that they are taking part in a study investigating the effects of a plant-based aroma, without any reference to the specific type of essential oil (lemon or bitter almond). This information will be clearly stated in the informed consent form. In the control group, a scentless bitter almond essential oil will be used, matched identically with the lemon oil in terms of bottle appearance, volume, color, and method of administration. Both types of essential oils will be prepared in sealed, coded envelopes by an individual not involved in the research team and assigned based on a randomization table. Participants will be aware that they are receiving one of two plant-based aromas, but they will not know whether they belong to the intervention or control group. Furthermore, no notable or perceivable difference in olfactory experience is expected, as the placebo will be presented as a "herbal extract" without drawing attention to the study design, thereby preserving participant blinding. The investigator and outcome assessor will also be blinded to the type of intervention through the use of anonymous codes and a randomization schedule generated by an independent third party. Similarly, the data analyst will analyze encrypted files without access to group allocation details.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Baqiyatallah Al'Azam Educational and Medical Center (Research Ethics Committee)
Street address
Baqiyatallah Al'Azam Hospital, After Sheikh Bahayi St., Molla Sadra Blvd., Vanak Square, Tehran
City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2025-04-28, 1404/02/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1404.057

Health conditions studied

1

Description of health condition studied

Postoperative Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2

Description of health condition studied

Postoperative Nausea and Vomiting

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

3

Description of health condition studied

Postoperative Pain

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Incidence of delirium within 72 hours after coronary artery bypass graft surgery

Timepoint

Delirium will be assessed the night before surgery (as baseline), immediately after the patient’s transfer to the cardiac intensive care unit, and then daily up to 72 hours following coronary artery bypass graft surgery.

Method of measurement

Delirium will be evaluated using the Intensive Care Delirium Screening Checklist by a nurse blinded to the intervention type. This tool consists of 8 items (altered level of consciousness, inattention, disorientation, hallucination-delusion-psychosis, psychomotor agitation or retardation, inappropriate speech or mood, sleep/wake cycle disturbance, and symptom fluctuation) used to diagnose delirium in patients admitted to the intensive care unit.

2

Description

Severity of pain within 72 hours after coronary artery bypass graft surgery

Timepoint

Pain intensity will be measured the night before surgery (as baseline), immediately after the patient’s transfer to the cardiac intensive care unit, and then at 6, 12, 24, 48, and 72 hours following coronary artery bypass graft surgery.

Method of measurement

Pain intensity will be measured using the Numeric Pain Rating Scale. The patient selects a number between zero (no pain) and 10 (worst possible pain) and circles it. Additionally, the location of pain and the amount of opioid consumption will be recorded.

3

Description

Severity of nausea and vomiting within 72 hours after coronary artery bypass graft surgery

Timepoint

Nausea and vomiting intensity will be measured the night before surgery (as baseline), immediately after the patient’s transfer to the cardiac intensive care unit, and then at 6, 12, 24, 48, and 72 hours following coronary artery bypass graft surgery.

Method of measurement

The intensity of nausea and vomiting will be measured using the Numeric Nausea and Vomiting Scale. The patient selects a number between zero (no nausea and vomiting) and 10 (worst possible nausea and vomiting) and circles it.

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" Patients will undergo inhalation aromatherapy with lemon essence. The lemon essence, with 100% purity, is produced by Barij Essence Company, and its quality will be verified by the Quality Control Unit of Baqiyatallah University of Medical Sciences using gas chromatography-mass spectrometry. The essence contains 2–6% volatile compounds, including limonene and citral. The intervention will begin the night before surgery. Five drops of lemon essence will be placed on a cotton pad and positioned approximately 10 cm from the patient’s nose. This procedure will be repeated every four hours until the induction of anesthesia by a trained nurse blinded to group allocation. After surgery, during nasal oxygen administration, five drops of the essence will be added to the flowmeter at a rate of 4 liters per minute, applied uniformly across all patients in the intervention group. Once spontaneous breathing resumes, the intervention will continue using the

previous method (five drops on a cotton pad placed 10 cm from the nose) every four hours until 24 hours after surgery. No intervention will be conducted during anesthesia induction or while the patient is intubated.

Category

Prevention

2

Description

"Control group:" Patients will undergo inhalation aromatherapy with odorless bitter almond oil as a placebo. This essence, with 100% purity, is produced by Barij Essence Company and is identical to lemon essence in terms of packaging, color, concentration, volume, and method of administration. The intervention procedure in this group is the same as in the intervention group, with the only difference being the use of bitter almond essence instead of lemon essence.The intervention will begin the night before surgery. Five drops of bitter almond essence will be placed on a cotton pad and positioned approximately 10 cm from the patient’s nose. This procedure will be repeated every four hours until the induction of anesthesia by a trained nurse who is blinded to group allocation.After surgery, during nasal oxygen administration, five drops of bitter almond essence will be applied via the flowmeter at a rate of 4 liters per minute. Once spontaneous breathing resumes, the intervention will continue using the same method (five drops on a cotton pad placed 10 cm from the nose) and will be repeated every four hours for up to 24 hours postoperatively. No intervention will be conducted during anesthesia induction or while the patient is intubated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Al'Azam Hospital

Full name of responsible person

Seyed Mohammad Reza Amouzegar Zavareh

Street address

Baqiyatallah Al'Azam Hospital, After Sheikh Bahayi St., Molla Sadra Blvd., Vanak Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Fooladi

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Siavash Sangi

Position

Master of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
Master of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Anesthesiology

Street address
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Only part of the data, such as information related to the main outcome or the like, can be shared.

When the data will become available and for how long
Access period 6 months after results are published.

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
No special conditions are considered.

From where data/document is obtainable
The person responsible for the study is Siavash Sangi. siavashsangi@gmail.com

What processes are involved for a request to access data/document
After receiving the qualified applicant's email, the documents will be sent within a short period of time.

Comments