Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of aromatherapy with rosemary and Mentha piperita essential oils on pain and hemodynamic indicators in patients after laparoscopic cholecystectomy

Protocol summary

Study aim
Comparing the effect of aromatherapy with rosemary and Mentha piperita essential oils on pain and hemodynamic indicators in patients after laparoscopic cholecystectomy

Design
This is a randomized, double-blind, placebo-controlled Phase III clinical trial. 93 patients, recruited via convenience sampling, will be allocated to treatment groups using block randomization.

Settings and conduct
Eligible patients admitted to Imam Khomeini Hospital in Arak and meeting all inclusion criteria for cholecystectomy will be randomly allocated to either the intervention or control groups using block randomization. This study will employ a double-blind design, with blinding maintained for the statistical analyst and the sample collector.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients (over 18 years) scheduled for elective cholecystectomy; normal sense of smell, speech, hearing, and vision; no allergy to peppermint or rosemary; no history of pulmonary or respiratory disorders; and postoperative pain intensity of three or higher on the Visual Analog Scale. Exclusion criteria: physical problems or hemodynamic instability; abnormal bleeding; unstable blood pressure; or undergoing any non-routine medical procedures.

Intervention groups
Intervention Group 1: Three drops of 100% peppermint essential oil (Giah Kala Co.) are placed on a sterile cotton pad and attached 20 cm from the patient's collar for 5–10 minutes of inhalation. Hemodynamic indices and Visual Analog Scale are measured before aromatherapy and at 5, 15, 30, and 60 minutes afterward. Group 2: Three drops of 25% rosemary essential oil (Giah Kala Co.) are used, and the control group receives three drops of scented distilled water. The timing and procedure are identical to Group 1.

Main outcome variables
Pain, Systolic Blood Pressure, Diastolic Blood Pressure, Respiratory Rate, Heart Rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260125068662N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date
2026-02-16, 1404/11/27

Registrant information

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Fatemeh Salehi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-09, 1404/11/20

Expected recruitment end date
2026-06-10, 1405/03/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of aromatherapy with rosemary and Mentha piperita essential oils on pain and hemodynamic indicators in patients after laparoscopic cholecystectomy

Public title
The Effect of Aromatherapy on Pain and Hemodynamic Indices
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients eligible for elective cholecystectomy surgery are adults (above 18 years of age) who have at least basic literacy (able to read and write) They must have no impairment of smell, speech, hearing, or vision no known allergy to peppermint or rosemary based on the initial patient interview and medical records Patients should have no history of pulmonary or respiratory diseases no substance abuse no use of anticoagulant medications no history of hypertension, and no psychiatric disorders. In addition, they should have no history of epilepsy or chronic headaches not be pregnant The postoperative pain intensity should be three or greater on the Visual Analogue Scale (Visual Analog Scale) Before starting the intervention, the effects of anesthesia must have completely worn off, and the patient should be fully conscious after the operation not connected to a ventilator, not receiving oxygen therapy, and able to breathe spontaneously
Exclusion criteria:
Use of analgesic or narcotic medications for pain relief beyond the routine postoperative orders. Presence of physical complications or instability in hemodynamic and physiological status, such as occurrence of cardiac arrhythmia, respiratory problems, abnormal bleeding blood pressure instability (including unusual increase or decrease during surgery or immediately after surgery in the recovery room), as well as any other abnormal condition reported by operating room staff or documented in the patient’s file.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be employed to ensure the concealment of treatment allocation. For this purpose, the SealedEnvelope website will be utilized. The total sample size, the number of study arms (groups), and the desired block sizes (blocks of 6) will be entered into the aforementioned website. The output will be a randomized list detailing the number of subjects allocated to each study group (Control and Intervention). Subsequently, each eligible research subject will be assigned a sequential code based on their order of presentation/enrollment. By matching this code with the generated block randomization list, participating patients will be allocated to either the Intervention Group or the Control Group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The essential oils (active agents) and the placebo will be placed in identical, opaque, and uniformly labeled bottles. Each bottle will be coded, with only the patient’s unique identification code inscribed upon it. All acquired data will be recorded and entered into the statistical software using only the patient identification codes. The statistical analyst responsible for data processing and analysis will not have access to the group codes (i.e., will remain blinded). The group allocation will only be revealed after the analysis is complete.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Khomein University of Medical Sciences
Street address
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3819749058
Approval date
2026-01-12, 1404/10/22
Ethics committee reference number
IR.KHOMEIN.REC.1404.039

Health conditions studied

1

Description of health condition studied
cholecystectomy
ICD-10 code
Z90.4
ICD-10 code description
Acquired absence of other parts of digestive tract

Primary outcomes

1

Description
Postoperative pain intensity based on Visual Analog Scale
Timepoint
before the intervention (aromatherapy) and at 5, 15, 30, and 60 minutes after aromatherapy
Method of measurement
visual Analog Scale (VAS) will be used to determine the presence and severity of pain

2

Description
Heart rate
Timepoint
Heart rate monitoring will be performed before the intervention (aromatherapy) and at 5, 15, 30, and 60 minutes after aromatherapy.
Method of measurement
A portable monitor is used to measure heart rate.

3

Description
Systolic blood pressure
Timepoint
Blood pressure control will be performed before the intervention (aromatherapy) and at 5, 15, 30, and 60 minutes after aromatherapy.
Method of measurement
Using a blood pressure monitor, portable monitor

4

Description
Respiratory rate
Timepoint
Breathing rate will be monitored before the intervention (aromatherapy) and at 5, 15, 30, and 60 minutes after aromatherapy.
Method of measurement
The number of breaths was also counted for one minute by the researcher using a stopwatch.

5

Description
Diastolic blood pressure
Timepoint
Blood pressure control will be performed before the intervention (aromatherapy) and at 5, 15, 30, and 60 minutes after aromatherapy.
Method of measurement
Using a blood pressure monitor, portable monitor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 3 drops of 100% Peppermint essential oil (for the mint group), prepared from the Giyah Kala company, are dropped onto a sterile cotton ball. This is attached to the patient’s collar at a distance of 20 cm, and the patient is instructed to perform deep inhalations for 5 to 10 minutes.
Category
Prevention

2

Description
Intervention group2 : 3 drops of 25% Rosmary essential oil (for the mint group), prepared from the Giyah Kala company, are dropped onto a sterile cotton ball. This is attached to the patient’s collar at a distance of 20 cm, and the patient is instructed to perform deep inhalations for 5 to 10 minutes.
Category
Prevention

3

Description
Control group: In the control group, the intervention is matched to the test group in terms of time and method of execution. The difference is that instead of the essential oil, 3 drops of scented distilled water will be used
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Arak
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Khomein 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
Khomein University of Medical Sciences

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Position
student

Latest degree
Bachelor

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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
No - There is not 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
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