

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of aromatherapy with Lavender on pain, anxiety and sleep quality after orthopedic surgery

Protocol summary

Study aim

Determining the effect of lavender inhalation aromatherapy on pain, anxiety and sleep quality after orthopedic surgery

Design

Clinical trial with control group, with parallel, randomized groups, on 80 patients. Random allocation software is used for randomization.

Settings and conduct

Patients admitted to orthopedic, trauma one and two wards of Ayatollah Kashani hospitals are admitted to the study on the second day after surgery and then are randomly assigned to the experimental and control groups. Inhalation aromatherapy intervention is performed for the intervention group. In this study, blinding is not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years and older Be interested in participating in research Elective and non-emergency surgery Patients with upper and lower limb fractures who have undergone surgery Exclusion criteria: History of lavender allergy (dermal or inhalation) Covid 19 disease based on PCR test results Have a history of allergic rhinitis, eczema or known respiratory problems such as asthma Do not be addicted to drugs

Intervention groups

The intervention group includes patients undergoing orthopedic surgery who will undergo aromatherapy with lavender, so that the samples participating in the study will undergo aromatherapy with lavender essential oil for 2 days and nights at 10 am and 6 pm. Thus, the researcher drops 3 drops of lavender essential oil produced by Barij Company with a dropper on a sterile cloth 10 cm by 10 cm and connects it to the collar of the research unit at a distance of 30 cm from the nose. The patient is then asked to breathe normally for 30 minutes. The comparison group includes patients after orthopedic surgery who will receive routine treatments and care.

Main outcome variables

the pain; Anxiety; Sleep quality of patients undergoing orthopedic surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111002007692N3**

Registration date: **2021-12-10, 1400/09/19**

Registration timing: **prospective**

Last update: **2021-12-10, 1400/09/19**

Update count: **0**

Registration date

2021-12-10, 1400/09/19

Registrant information

Name

tahere momeni

Name of organization / entity

Isfahan university of medical science

Country

Iran (Islamic Republic of)

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+98 913 239 0798

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with Lavender on pain, anxiety and sleep quality after orthopedic surgery

Public title
The effect of aromatherapy with Lavender on pain, anxiety and sleep quality

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18 years and older Be interested in participating in research Positive olfactory test (ability to detect the smell of the desired aromatherapy solution) Elective and non-emergency surgery Patients with upper and lower limb fractures who have undergone surgery Community
Exclusion criteria:
 History of lavender allergy (dermal or inhalation) Covid 19 disease based on PCR test results (currently the hospital requires PCR testing for all patients undergoing surgery) Have a history of allergic rhinitis, eczema or known respiratory problems such as asthma Having a cold or any other condition that affects a person's ability to smell. Do not be addicted to drugs Using other methods of reducing stress, including progressive muscle relaxation, music therapy, etc. Smoking Use of specific medication for psychiatric illness Simultaneous collaboration in another similar study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Block randomization with size of 4. Randomization unit: individual. Randomization tool: Random allocation software. Random chain concealment is by placing patient codes in opaque envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

Isfahan University of Medical Sciences,Isfahan,Iran

City

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Isfahan

Postal code

81746-73461

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.628

Health conditions studied

1

Description of health condition studied

Fracture of upper limb, level unspecified

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb, level unspecified

2

Description of health condition studied

Fracture of lower limb, level unspecified

ICD-10 code

T12

ICD-10 code description

Fracture of lower limb, level unspecified

Primary outcomes

1

Description

Pain score based on linear scale

Timepoint

Immediately before and after each intervention

Method of measurement

American 10-item pain intensity measurement questionnaire Patient Outcomes Pain community

Secondary outcomes

1

Description

Score from the Anxiety Inventory

Timepoint

Immediately before and after the intervention

Method of measurement

spielberger anxiety scale

2**Description**

Score from the sleep quality questionnaire

Timepoint

Immediately before and after the intervention

Method of measurement

SMHSQ standard hospital sleep questionnaire

Intervention groups**1****Description**

Intervention group: In the experimental group, the samples participating in the study are subjected to aromatherapy with lavender essential oil for 2 days and nights at 10:00 AM and 6:00 PM. Thus, the researcher drops 3 drops of lavender essential oil, produced by Barij Essential Oil Company of Kashan, with a dropper on a sterile cloth measuring 10 cm by 10 cm and attaches it to the collar of the research unit at a distance of 30 cm from the nose. The patient is asked to breathe normally for 30 minutes; their pain is recorded immediately before and after each aromatherapy, and their anxiety and sleep quality are measured immediately before and after the intervention.

Category

N/A

2**Description**

Control group: The control group will receive inpatient treatment and routine care, and like the sleep quality test group, their pain and anxiety will be assessed by questionnaires at the same time intervals.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Kashani Hospital of Isfahan University of Medical Sciences

Full name of responsible person

Tahere Momeni-Ghaleghasemi

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Isfahan, Ayatollah Kashani Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Tahere Momeni-Ghaleghasemi

Position

مربی هیات علمی

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be 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