Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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

Isfahan

Province

Isfehan

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
Street address
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
Dr. Mansour Siavash
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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
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Person responsible for updating data

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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