Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

assessing the effect of inhalation of aromatherapy (Citrus aurantium) on post-operative pain after orthopedic surgery in lower limb

Protocol summary

Study aim
To determine the effect of aromatherapy with citrus aurantium essential oil on pain after orthopedic surgery

Design
Experimental triple blind clinical trial study

Settings and conduct
This study is a randomized controlled clinical trial performed on 60 candidates for orthopedic surgery in Ayatollah Mousavi Hospital in Zanjan. In this study, patients were selected through convenience sampling based on inclusion criteria and then they were divided into intervention and control groups through randomized block allocation. Visual analogue scale (VAS) was used to collect data. The Pain was measured and recorded in both groups 4, 8 and 12 hours after surgery using VAS tool. If the VAS score was above 3, patients in the intervention group received aromatherapy with Citrus aurantium essential oil and the patients in the control group received aromatherapy with placebo (almond oil). During these three stages of intervention, 20 minutes after aromatherapy, pain was re-evaluated in both experimental and control groups using VAS.

Participants/Inclusion and exclusion criteria
Inclusion criteria :Desiring to participate in the study - Having full awareness and cooperation - Healthy smell status - Not having: Coagulation disorder, Diabetes, Breathing disorder - Not having a history of allergy to plants - Having a fracture of the lower part of the femur and legs- Healthy visual and mind status to see and understand VAS tool - Not having surgery history Being older than 15 years old and older - Not having previous surgical experience and no drug addiction. Exclusion criteria :Complications of post- surgery (bleeding, hematoma at the site of surgery) Need to oxygen therapy after surgery

Intervention groups
The patients will be randomly divided into 2 groups: the first group will inhale 10% Citrus aurantium essential and the second group will inhale sweet almond

Main outcome variables
Post-operative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140304016843N13**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **retrospective**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

Registration date
2021-01-01, 1399/10/12

Registrant information

Name
Nasrin Bahraminejad

Name of organization / entity
Zanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-29, 1397/08/07

Expected recruitment end date
2019-02-10, 1397/11/21

Actual recruitment start date
2018-10-29, 1397/08/07

Actual recruitment end date

2019-02-09, 1397/11/20

Trial completion date

2019-03-09, 1397/12/18

Scientific title

assessing the effect of inhalation of aromatherapy (Citrus aurantium) on post-operative pain after orthopedic surgery in lower limb

Public title

The effect of inhalation of aromatherapy (Citrus aurantium) on postoperative pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Desiring to participate in the study - Having full awareness and cooperation - Healthy smell status - Not having: Coagulation disorder, Diabetes, Breathing disorder - Not having a history of allergy to plants - Having a fracture of the lower part of the femur and legs- Healthy visual and mind status to see and understand VAS tool - Not having surgery history Being older than 15 years old and older - Not having previous surgical experience and no drug addiction

Exclusion criteria:

Complications of post- surgery (bleeding, hematoma at the site of surgery) Need to oxygen therapy after surgery Patient’s unwillingness to participate in the study after first intervention

Age

From **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Candidate patient for orthopedic surgery will be selected through convenience sampling and will be divided into experimental and control groups by block random allocation method. To create two identical groups, first for each of group will be allocated letters A and B. Size of blocks will be four. After itemizing approximate all possible modes of 4 blocks (AABB, ABAB, BABA, BBAA, ABBA, BAAB) and assigning a number to each one, based on a random number table, 15 blocks will select to increase the number of samples to 60 people (30 people in the experimental group, 30 people in the placebo group). To allocate patients in the experimental or control groups, the type of intervention will be written on the envelope group A (i.e., Citrus aurantium) and group B (i.e., placebo). Envelopes will be arranged sequentially in random order. The patient will allocate to either of the groups based on the envelope label.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients will be informed that they will participate in study but they will not know that they are in the experimental group or in the control group. Research assistances who will perform the intervention or evaluate the results of the intervention will not know that which group are the experimental group and which group are the control group .Citrus aurantium and placebo will be given to research assistants in the form two containers with the names A and B and will not be given explanatory about content of the container for them. Also, the research assistant who assessed pain after the intervention will not be informed of the experimental or control groups. The experimental and control groups will be introduced to someone who analyzes the results as groups A and B. Though, the fragrance of Citrus aurantium and sweet almond oil are different. But none of the patients knew they will in the experimental or control group. Also, for the research assistant who performed the intervention, Citrus aurantium will again introduce as drug A and almond oil as drug B. As mentioned earlier, the fragrance of Citrus aurantium is not the same as almond oil .The almond oil was selected as a placebo based on the opinion of an expert in pharmacognosy, because almond oil is not volatile and cannot be absorbed by inhalation. In addition, during the intervention, patients will be in a separate room in the intervention and control groups. On the other hand, patients will not know whether they are in the control group or in the control group

Placebo

Used

Assignment

Parallel

Other design features

Experimental triple blind clinical trial study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi blvd

City

Zanjan

Province

Zanjan

Postal code

4581955159

Approval date
2018-05-07, 1397/02/17
Ethics committee reference number
IR.ZUMS.REC.1397.015

Health conditions studied

1

Description of health condition studied
post-operative pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
post operative pain
Timepoint
In 4, 8, and 12 hours after the transfer of the patient from the operating room to the surgical unit
Method of measurement
Visual analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group, if the patients who underwent lower orthopedic surgery, their pain score by using VAS instrument was more than 3 after 4,8,12 hours after surgery, 4 drops of Citrus aurantium essential oil was poured on a cotton ball and the patient was asked to inhale it for 5 minutes at a distance of 20 CM. Then, after 20 minutes, the pain intensity was measured again on the visual analogue scale.
Category
Treatment - Other

2

Description
Control group: In the control group, similar to the intervention group at 4.8,12 hours after surgery, the severity of pain was assessed using the VAS instrument. If their postoperative pain score was more than 3, they were treated with sweet almond oil and then 20 minutes later - similar to experimental group, their pain intensity was assessed and recorded. Patients in both groups also received routine medications to relieve pain. Patients selected for experimental group were evaluated for allergy to Citrus aurantium essential oil by skin patch test containing Citrus aurantium before intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
orthopedic surgery ward in Ayatollah Mousavi Hospital in Zanjan
Full name of responsible person
Sepideh barghi
Street address
Educational and treatment center of Ayatollah Mousavi, Gavazang road
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Alireza Shoghli
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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
Zanjan University of Medical Sciences
Proportion provided by this source
80
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

Zanjan University of Medical Sciences

Full name of responsible person

Sepideh Barghi

Position

MS student in medical- surgical nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Nasrin Bahraminejad

Position

استادیار

Latest degree

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Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Full name of responsible person

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Associated prof

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

Data sharing will be exclusively for Zanjan University of Medical Sciences

When the data will become available and for how long

Up to 6 months after the completion of the project

To whom data/document is available

Researchers working in Zanjan University of Medical Sciences

Under which criteria data/document could be used

To do more research in this area with the permission of the Vice Chancellor for Research of Zanjan University of Medical Sciences

From where data/document is obtainable

Nursing and Midwifery Faculty, Mahdavi Blvd, Karmandan settlement s.barghi7070@gmail.com

What processes are involved for a request to access data/document

Submit a request to the Vice Chancellor for Research of Zanjan University of Medical Sciences

Comments