

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

Country

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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	(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.
Scientific title assessing the effect of inhalation of aromatherapy (Citrus aurantium) on post-operative pain after orthopedic surgery in lower limb	Blinding (investigator's opinion) Double blinded
Public title The effect of inhalation of aromatherapy (Citrus aurantium) on postoperative pain	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
Purpose Supportive	Placebo Used
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	Assignment Parallel
Age From 15 years old	Other design features Experimental triple blind clinical trial study
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	Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee of Zanzan University of Medical Sciences Street address Zanzan University of Medical Sciences, Azadi blvd City Zanzan Province Zanzan 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

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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
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Person responsible for updating data

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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