Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of lemon essence on anxiety, physiological indices and post-operative nausea & vomiting in patients undergoing lower limb fractures surgeries

Protocol summary

Study aim
Determine the effect of lemon essence on anxiety, physiological indices and post-operative nausea & vomiting in patients undergoing lower limb fractures surgeries

Design
A clinical trial with control group, parallel group randomized trial, a single blinded

Settings and conduct
Setting: Rajai, and Namazi hospitals, Data collector and statistician are blind.

Participants/Inclusion and exclusion criteria
The inclusion criteria would be having lower limb fracture surgery, being hospitalized in Orthopedic surgery Wards for 24 hours before surgery, being 18 years old or above, and being oriented to time, person and place. The patient has an asthma, a respiratory allergy or be sensitive to extracts of the plant, has olfactory problems, and nasal injury, being known case of psychological diseases, participated in previous studies received complementary and alternative interventions from a week before the intervention, transfer to ICU after surgery, requires postoperative ventilator, and died would be excluded.

Intervention groups
Intervention group: Take five drops of lemon essence on a cotton pad and attached to the patient's collar with a pin at a distance of 20 cm from the head. Aromatherapy starts in the morning of the lower limb fracture surgery and will be extended at two-hour intervals until the end of the surgery, in recovery and 16 hours after surgery. Control group: Bitter almond oil, which is odorless, will be used in a similar way of the intervention group.

Main outcome variables
Anxiety, physiological indices and post-operative nausea & vomiting

General information

Reason for update
Change in the time of start the intervention and setting of study

Acronym

IRCT registration information
IRCT registration number: **IRCT20130616013690N10**
Registration date: **2021-07-24, 1400/05/02**
Registration timing: **prospective**

Last update: **2021-12-15, 1400/09/24**
Update count: **1**

Registration date
2021-07-24, 1400/05/02

Registrant information

Name
Masoume Rambod

Name of organization / entity
Shiraz University of Medical Science

Country
Iran (Islamic Republic of)

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+98 71 1647 4258

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rambodm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-16, 1400/09/25

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lemon essence on anxiety, physiological indices and post-operative nausea & vomiting in patients undergoing lower limb fractures surgeries

Public title

The effect of lemon essence on patients undergoing lower limb fractures surgeries

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having Lower Limb Fracture Surgery Hospitalization in orthopedic surgery Wards for 24 hours before surgery Being 18 years old or above Being oriented to time, person and place

Exclusion criteria:

Patient has an asthma, a respiratory allergy or be sensitive to extracts of the plant The patient has olfactory problems, and nasal injury Being known case of psychological diseases (major depression, anxiety, psychosis, etc.) Participated in previous studies received complementary and alternative interventions from a week before the intervention Transfer to ICU after surgery Requires postoperative ventilator Death of the patient

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, Rajai and Namazi hospitals are selected as two separate strata. Then, using Winpepi software and balanced randomization of separate strata, a list of random allocation is set for 90 patients. Therefore, according to the list in each stratum (hospital), 45 patients are randomly divided into the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

To conducting blinding, assistant researcher who collects data, as well as statistician who analyzes the data, are blinded to the groups and the assignment of individuals in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery, Management and Medical Information Sc

Street address

Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

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Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.001

Health conditions studied

1

Description of health condition studied

Lower limb fracture surgery

ICD-10 code

T84.11

ICD-10 code description

Breakdown (mechanical) of internal fixation device of bones of limb

Primary outcomes

1

Description

Anxiety

Timepoint

In the morning of the surgery and the day after surgery at 8 A.M.

Method of measurement

State-Trait Anxiety Inventory

2

Description

Physiological indices (blood pressure, SPO2, respiration, temperature and pain)

Timepoint

In the morning of surgery, In the post-operative anesthesia care unit, after entering the orthopedic ward, and 4, 8, 12 and 16 hours after surgery

Method of measurement

Digital blood pressure monitors, Pulse Oximeter, Chronometer, MASTECH Non Contact Infrared Medical Thermometer and numeric analogue pain

3

Description

Neurovascular assessment of lower limb

Timepoint

In the morning of surgery, after entering the orthopedic ward, and 4, 8, 12 and 16 hours after surgery

Method of measurement

WACHS Neurovascular Observation Charts

4

Description

Post-operative nausea and vomiting

Timepoint

In the post-operative anesthesia care unit, 4, 8, 12 and 16 hours after surgery

Method of measurement

Rhodes Index of Nausea, Vomiting and Retching and Numeric Analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take five drops of lemon essence on a cotton pad and attached to the patient's collar with a pin at a distance of 20 cm from the head. Aromatherapy starts in the morning of the lower limb fracture surgery and will be extended at two-hour intervals until the end of the surgery, in recovery room and 16 hours after surgery.

Category

Prevention

2

Description

Control group: Bitter almond oil, which is odorless, will be used in a similar way of the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajai hospitals

Full name of responsible person

Masoume Rambod

Street address

Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz

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2

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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Grant name

23210

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Masoume Rambod

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Primary outcomes would be shared.

When the data will become available and for how long
Starting 6 months after publication article

To whom data/document is available
People and researchers working in academic institutions

Under which criteria data/document could be used

Data are provided for information only.

From where data/document is obtainable

Data is available via email rambodma@yahoo.com.

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

Data is available via email rambodma@yahoo.com.

Comments