

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of inhaled *Rosa damascena* (Damask Rose) aromatherapy on the severity of anxiety in adults following lower extremity orthopedic surgery

Protocol summary

Study aim

Analyzing the effect of aromatherapy using rose essential oil on anxiety levels after general anesthesia in ankle bimalleolar fracture surgery.

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized using dice, in two groups of 50 people.

Settings and conduct

This study will be performed on ASA I, and II patients undergoing bimalleolar surgery. After obtaining consent, all patients over 18 who refer to the operating room of Imam Hossein (AS) Hospital in Tehran in 2022-2023 for surgery will be included in the study. Inhalation intervention will be performed 30 minutes before general anesthesia. An anesthesia technician randomly selects one of the groups for the patient with the help of a coin toss.

Participants/Inclusion and exclusion criteria

After the approval of the ethics committee of Shahid Beheshti University of Medical Sciences and after obtaining the informed consent of the patients, all patients over 18 years of age referred to the operating room for ankle bimalleolar surgery were examined. Patients with olfactory dysfunction, allergy to rose, smokers, and those using illicit drugs were excluded from the study.

Intervention groups

In the intervention group, thirty minutes before general anesthesia, three drops of essential oil of rose are poured on a napkin and the patient inhales it for ten minutes at a distance of 10 cm. In the control group, the same method was used, but instead of essential oil, three drops of drinking water will be used.

Main outcome variables

severity of the patient's anxiety after entering recovery, assess the amount of pain and the presence of nausea

and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010800N7**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **prospective**

Last update: **2022-11-07, 1401/08/16**

Update count: **0**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Dariush Abtahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2263 2611

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-02-09, 1401/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhaled Rosa damascena (Damask Rose) aromatherapy on the severity of anxiety in adults following lower extremity orthopedic surgery

Public title

The effect of inhaling rose essential oil on postoperative agitation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA physical status classification I and II Bimalleolar ankle surgery Consent to participate to trial

Exclusion criteria:

Patients using other methods of relaxation Olfactory disorders Allergy to roses Smoking Drug abusers

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected by simple randomization method using a coin toss. In such a way that the selection of the case is done in the case of heads and the selection of control is done in the case of tails.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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 - Shahid Beheshti University of Me

Street address

Emam Hossein Hospital, Shahid Madani St.

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2022-10-02, 1401/07/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.472

Health conditions studied

1

Description of health condition studied

bimalleolar ankle surgery

ICD-10 code

S82.84

ICD-10 code description

Bimalleolar fracture of lower leg

Primary outcomes

1

Description

agitation

Timepoint

postoperative, in recovery room

Method of measurement

Observation and self-declaration

Secondary outcomes

1

Description

pain

Timepoint

postoperative, in recovery room

Method of measurement

Pain ruler, visual analog scale

2

Description

postoperative nausea and vomiting

Timepoint

at 24 hours after the end of surgery

Method of measurement

Observation and self-declaration

Intervention groups

1

Description

Intervention group: Thirty minutes before general anesthesia, three drops of 33% rose essential oil (Barij Essential Oil Company) are poured on a cloth and the patient takes it at a distance of ten centimeters and inhales it for ten minutes. The studied variables will be

examined in the recovery room.

Category

Prevention

2**Description**

Control group: Thirty minutes before general anesthesia, three drops of water are poured on a cloth and the patient takes it at a distance of ten centimeters and inhales it for ten minutes. The studied variables will be examined in the recovery room.

Category

Placebo

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

Hospital Emam Hossein

Full name of responsible person

Dariush Abtahi

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshhin Zarghi

Street address

Tehran Province, Tehran, Velenjak, 7th Floor, Bldg
No.2 SBUMS, Arabi Ave

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Phone

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Email

Intl_office@sbmu.ac.ir

Web page address

<https://en.sbmu.ac.ir>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dariush Abtahi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identified individuals.

When the data will become available and for how long

One year after the publication of the article.

To whom data/document is available

All jobs

Under which criteria data/document could be used

All non-personal patient information (anonymously) can be accessed by contacting the responsible author.

From where data/document is obtainable

email to: drdariushabtahi@yahoo.com

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

Sending email and review by the responsible author.

Comments