Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between the effect of aromatherapy with Chamomile and Damask Rose (Rosa damascene mill) on anxiety and pain in emergency surgery patients

Protocol summary

Study aim

Comparison of the effect of aromatherapy with Damask rose and chamomile essential oil on anxiety level, pain intensity and hemodynamic variables in patients candidates for emergency surgery.

Design

This study will be a randomized clinical trial with three groups (two intervention groups and one control group).To allocate the samples to the study groups randomly, the random permutation block design of three treatments with six blocks will be used; which will be considered A (for the frozen flower group), B (for the chamomile group) and C (for the control group). Then the website https://www.sealedenvelope.com will be used to determine the required random blocks and their sequence.

Settings and conduct

The research environment will be the male and female surgery wards of Zanjan medical science teaching hospitals.

Participants/Inclusion and exclusion criteria

People over 18 years of age (to ensure the expressed sense), The patient's desire to participate in the study, Having clear verbal ability, Not having a history of allergy and sensitivity to chamomile and Damask rose, Having a healthy sense of smell and Having no history of surgery on the jaw, face and nose and systemic or chronic diseases affecting the sense of smell or hearing, There is no history of mental illness and chronic anxiety diseases known based on the patient's speech and his family.

Intervention groups

Aromatherapy group with Damask rose essential oil (group A) - Aromatherapy group with chamomile essential oil (group B) - Control group with distilled water (group C)

Main outcome variables

Anxiety; Pain; Vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220827055802N1**
Registration date: **2022-09-14, 1401/06/23**
Registration timing: **prospective**

Last update: **2022-10-01, 1401/07/09**
Update count: **1**

Registration date

2022-09-14, 1401/06/23

Registrant information

Name

Farshid Bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3575 4193

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farshidbh72129@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison between the effect of aromatherapy with Chamomile and Damask Rose (Rosa damascene mill) on anxiety and pain in emergency surgery patients

Public title
Comparison between the effect of aromatherapy with Chamomile and Damask Rose (Rosa damascene mill) on anxiety and pain in emergency surgery patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- People over 18 years of age (to ensure the expressed sense) 2- The patient's desire to participate in the study 3- Having clear verbal ability

Exclusion criteria:
1- having a history of allergy and sensitivity to chamomile and Damask Rose 2- There is history of mental illness and chronic anxiety diseases known based on the patient's speech and his family. 3- Unhealthy sense of smell and having a history of surgery on the jaw, face and nose and systemic or chronic diseases affecting the sense of smell or hearing

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate the samples to the study groups randomly, a random permutation block design of three treatments with six blocks will be used, which is A (for the Damask Rose group), B (for the chamomile group) and C (for the control group) will be considered. Then, the website: https://www.sealedenvelope.com will be used to determine the required random blocks and their sequence.

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
Ethics committee of Zanjan University of Medical Sciences

Street address
No 73-beheshti street- hidaj city-zanjan province

City
Zanjan

Province
Zanjan

Postal code
4573155641

Approval date
2022-08-23, 1401/06/01

Ethics committee reference number
IR.ZUMS.REC.1401.183

Health conditions studied

1

Description of health condition studied
All candidates for emergency surgery in the field of orthopedics with a closed injury of a limb, such as fractures and sprains, tendon injuries, and joint and ligament injuries in the hands or feet.

ICD-10 code
G89.11

ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Anxiety level on the visual analogue scale of anxiety

Timepoint
Measuring the level of anxiety before the intervention, after three intervention periods, in the morning before the operation

Method of measurement
Visual Analogue Scale of Anxiety

2

Description
Pain intensity on a visual analog scale

Timepoint
Pain intensity measurement before the intervention, after three intervention periods, in the morning before the operation

Method of measurement
visual analog scale

Secondary outcomes

1

Description

Vital Signs

Timepoint

Before and after performing 3 intervention courses and on the morning of the operation day while transferring the patient to the operating room

Method of measurement

A nurse will be used to count the patient's breaths in one minute. For pulse and blood pressure, the standard portable monitor device calibrated by the medical equipment unit of the hospital will be used by the same nurse

Intervention groups

1

Description

The first intervention group: Damask rose group, the use of 40% Damask rose essential oil as aromatherapy, the total time of the intervention at the night before the operation is 3 times each time for 1 hour, with 3 drops in each hour and a total of 9 drops in 3 hours. The essential oil purchased from Zarband company will be used

Category

Treatment - Drugs

2

Description

The second intervention group: Chamomile group, the use of 40% Chamomile essential oil as aromatherapy, the total time of the intervention at the night before the operation is 3 times each time for 1 hour, with 3 drops in each hour and a total of 9 drops in 3 hours. The essential oil purchased from Zarband company will be used

Category

Treatment - Drugs

3

Description

Control group: Distilled water group, use of distilled water as aromatherapy, the total time of the intervention the night before the operation is 3 times for 1 hour each time, where 3 drops will be used every hour and a total of 9 drops will be used in 3 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational & Treatment Center of mosavi

Full name of responsible person

Dr. Mostafa Azizi

Street address

Ayat Mousavi hospital, Gavazang Road

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2

Recruitment center

Name of recruitment center

Alghadir Abhar Hospital

Full name of responsible person

Dr. Javad Hosseinkhani

Street address

next to the nursing faculty, Nurse Blvd, at the end of Ayatollah Khamenei Blvd, Abhar city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Hassan Bakhtiari

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Zanjan University of Medical Sciences, Azadi Blvd, Zanjan

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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
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

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable