

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of aromatherapy with Damask rose on pain and anxiety in elderly individuals undergoing knee joint replacement surgery (total knee arthroplasty)

Protocol summary

Summary

This study is a non-randomized clinical trial. The aim of this study is to determine the effect of aromatherapy with Damask rose on pain and anxiety in elderly individuals undergoing knee joint replacement surgery (total knee arthroplasty). The study population are women and men aged over 60 years who have undergoing knee replacement surgery. The sampling is done continuously available. target sample size is 80 and trial recruitment centers are Moheb and Safa hospitals. inclusion criterias are no history of asthma and allergies, lack of sensitivity to Damask rose, patient's ability to self-reporting, lack of mental disorders (psychosis, dementia, delirium) that will be measured by abbreviated mental test score (AMTs), age over 60 years, no alcohol and substance abuse, healthy sense of smell (olfactory test +), no history of migraine and chronic headache and the ability to count numbers. Exclusion criterias are: lack of willingness to continue cooperation, respiratory allergy symptoms during the study, critically ill patient during the study, surgical wound infection, dislocation of the implant and the need for reoperation, patients who are hospitalized in the ICU for more than 24 hours after surgery. Patients in the intervention group will receive 4 periods of inhalation aromatherapy with Damask rose. Duration of Each period will be one or two minuets. Distance between each period is 30 minutes. The whole intervention will be done in 2 hours. Patient in control group will receive distilled water instead of Damask rose. Before the first intervention demographic form, ATMs questioner and pretest for pain and anxiety will be completed. immediately after the fourth intervention pain and anxiety will be evaluated by posttest.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030832950N1**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Parvaneh Samady Kia

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research & Technology-Iran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Damask rose on pain and anxiety in elderly individuals undergoing knee joint replacement surgery (total knee arthroplasty)

Public title

The effect of aromatherapy on pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: no history of asthma and allergies, lack of sensitivity to Damask rose, patient's ability to self-reporting, lack of mental disorders (psychosis, dementia, delirium) that will be measured by abbreviated mental test score (AMTs), age over 60 years, no alcohol and substance abuse, being healthy sense of smell (olfactory test +), no history of migraine and chronic headache and the ability to count numbers. Exclusion criteria: lack of willingness to continue cooperation, respiratory allergy symptoms during the study, critically ill patient during the study, surgical wound infection, dislocation of the implant and the need for reoperation, patients who are hospitalized in the ICU for more than 24 hours after surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, between the intersection of Chamran and Sheikh fazl o lah, Hemat highway

City

Tehran

Postal code

1449614535

Approval date

2016-06-29, 1395/04/09

Ethics committee reference number

IR.IUMS.REC.1395.9411580004

Health conditions studied**1****Description of health condition studied**

Knee joint replacement

ICD-10 code

M17

ICD-10 code description

arthrosis of knee

Primary outcomes**1****Description**

pain

Timepoint

Before the first intervention and Immediately after the fourth intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

anxiety

Timepoint

Before the first intervention and Immediately after the fourth intervention

Method of measurement

Visual Analogue Scale-Anxiety

Intervention groups**1****Description**

The intervention group (Aromatherapy with Rose): 3 to 4 drops of essential oil of Rose are poured on a 10×10 gauze pad and the pad is placed inside a zippered plastic bag. Then the patient is asked to inhale the bag for a minute. This intervention is done four times. the distance between each session is 30 minutes. The intervention is done in 2 hours.

Category

Treatment - Drugs

2

Description

The control group (Receiving placebo): 5 ml of distilled water are poured on a 10×10 gauze pad and the pad is placed inside a zippered plastic bag. Then the patient is asked to inhale the bag for a minute. This intervention is done four times. The distance between each session is 30 minutes. The whole process is done in 2 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Mehr Hospital

Full name of responsible person

Fateme Khani

Street address

Khalilzadeh st, Vali asr st, vanak sq

City

Tehran

2

Recruitment center

Name of recruitment center

Shafa Yahyaeian Orthopedics Hospital

Full name of responsible person

Atefe Dastory

Street address

Shafa Yahyaeian Orthopedics Hospital, Mojahedin
Islam Ave. Shohada Sq. Baharestan Sq. Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology-Iran
University of Medical Sciences

Full name of responsible person

Doctor Morteza Naserbakht

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Iran University of Medical Sciences, 5th Floor,
between intersection of Chamran and Sheikh fazl o
lah, Hemat Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research & Technology-Iran

University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing school, Iran University of Medical Sciences

Full name of responsible person

Faridah Bastani

Position

PHD-Professor

Other areas of specialty/work

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Full name of responsible person

Parvaneh Samady kia

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty