Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Assessing the effect of aromatherapy (Rosa damascene essence) on the postoperative pain intensity of inguinal hernia repair

Protocol summary

Study aim
Assessing the effect of aromatherapy (Rosa damascene essence) on the post-operative pain intensity of inguinal hernia repair

Design
Clinical trial study, randomized, double blind, duplicate and having control groups. Each group of 30 patients was designed from July to October, 2018.

Settings and conduct
The statistical population is the patients after inguinal hernia surgery in the surgical ward of Amiralmomenin Hospital in Qeydar, Iran. After surgery and transferring the patients to ward, we will measure score pain of patients by visual analog scale (VAS) within 4,8,12 hours after surgery and if pain score was upper than 3 the patients will receive rosa damascene (experimental group) and sweet almond oil(control group) and their score pain will be measured again and the result will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: desiring to participate in the study, having inguinal hernia surgery, not having surgery history, having full awareness and cooperation, healthy smell status, healthy visual and mind status to see and understand VAS tool, being older than 18 years old and older, being able to understand Persian or Turkish language, Not having a history of allergy to plants, not having: Pregnancy, Hypertension, Coagulation disorder, Diabetes, Breathing disorder. Not having moderate to severe anxiety and not taking analgesic and anti- anxiety drugs and no addiction. Exclusion criteria: complications of post- surgery (bleeding, hematoma at the site of surgery), need to oxygen therapy after surgery, and patient's unwillingness to participate in the study after first intervention

Intervention groups
The patients will be randomly divided into 2 groups: the first group will inhale 40% rosa damascene essence 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: **IRCT20140304016843N12**
Registration date: **2018-07-28, 1397/05/06**
Registration timing: **prospective**

Last update: **2018-07-28, 1397/05/06**
Update count: **0**

Registration date
2018-07-28, 1397/05/06

Registrant information

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Name of organization / entity
Zanjan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of aromatherapy (Rosa damascene essence) on the postoperative pain intensity of inguinal hernia repair

Public title

The effect of aromatherapy with Rosa damascene on post-operative pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Desiring to participate in the study Having inguinal hernia surgery Not having surgery history Having full awareness and cooperation Healthy smell status Healthy visual and mind status to see and understand VAS tool Being older than 18 years old and older Being able to understand Persian or Turkish language Not having a history of allergy to plants Not having: Pregnancy, Hypertension, Coagulation disorder, Diabetes, Breathing disorder Not having moderate to severe anxiety and not taking analgesic and anti- anxiety drugs No 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

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Candidate patient for inguinal hernia surgery will be selected through convenience sampling and with Block random allocation method will be applied to the case and control groups. we use of block randomization To create two identical groups, first for each of group will be allocated letters A and B. size of blocks will be foursome, After the list of all possible modes and assign a number to each one, some block will be selected through Table of random numbers until number of sample to be 60

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients will be informed that they will participate in study but they will not notice that they are in the case group or in the control group. Samplers will not notice that which group are the case group and which group are the control group (materials required for intervention will be given to samplers 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, nurses are working in the department will not be informed of the case or control groups.

Placebo

Used

Assignment

Parallel

Other design features

Experimental double blind clinical trial study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi blvd

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Province

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Postal code

4581955159

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.ZUMS.REC.1397.20

Health conditions studied

1

Description of health condition studied

Post-operative pain

ICD-10 code

ICD-10 code description

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

VAS (Visual analog Scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this study, Intervention will be done in the form aromatherapy with Rosa damascene essence. After we have found that the result of skin sensitivity test for essence is negative, pain score of patient will be checked with visual analog scale (VAS) in 4,8,12 hours after surgery and if pain score of patients was upper than 3, five drops of Rosa damascene essence will be poured on cotton ball and pinned to the patient's shirt and Patients will inhale it for 20 minutes at a distance of 20 cm, then pain score will be measured with visual analog scale again. In all three interventions, if pain score of patient after aromatherapy was upper than 3, the patients will receive routine analgesics by the staff.

Category
Treatment - Drugs

2

Description
Control group: in control group, patient will receive aromatherapy like experimental group but this group will receive Sweet Almond Oil (placebo) instead of Rosa damascene essence and pain score of patients will be measured similar to the experimental group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Abolfazl amini

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Sponsors / Funding sources

1

Sponsor

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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

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
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Position
دانشجوی کارشناسی ارشد پرستاری داخلی جراحی

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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