

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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 Amirmomenin 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

##### Name

Nasrin Bahraminejad

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3314 8325

##### Email address

bahrami\_n@zums.ac.ir

##### 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

##### City

Zanjan

##### Province

Zanjan

##### 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

##### Street address

Amiralmomenin Hospital, Shafa Street

##### City

Qeydar

##### Province

Zanjan

##### Postal code

4581955159

##### Phone

+98 24 3422 1693

##### Email

amini.abolfazle@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr Alireza Shoghli

##### Street address

Zanjan University of Medical Sciences, Azadi square

##### City

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##### Postal code

4581955159

##### Phone

+98 24 3315 6570

##### Email

amini.abolfazle@gmail.com

#### 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

Abolfazl Amini

##### Position

دانشجوی کارشناسی ارشد پرستاری داخلی جراحی

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Nursing and Midwifery Faculty, Mahdavi Blvd,  
Karmandan settlement

##### City

Zanjan

##### Province

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##### Postal code

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##### Phone

+98 24 3314 8300

##### Email

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Nasrin Bahraminejad

**Position**

Ph.D

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

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**Position**

Ph.D.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Mahdavi Blvd,  
Karmandan settlement

**City**

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**Province**

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**Postal code**

Iran

**Phone**

+98 24 3314 8325

**Email**

bahrami\_n@zums.ac.ir

## 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