

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of heat therapy and aromatherapy with lavender essential oil on shoulder pain after laparoscopic cholecystectomy

Protocol summary

Study aim

Determining the effect of two methods of heat therapy and aromatherapy with lavender essence on shoulder pain after laparoscopic cholecystectomy

Design

In this clinical trial, 96 patients who are candidates for laparoscopic cholecystectomy are randomly selected. Participants are randomly divided into two intervention groups based on a Random Digital Table and a control group with parallel groups and blindly on one side.

Settings and conduct

The place of intervention is in the operating room of Al-Zahra and Amin hospitals in Isfahan, The statistical analyst is not aware of the study groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidates for laparoscopic cholecystectomy surgery. Exclusion criteria: allergy to the essence of lavender; patient's intention to leave the intervention at any time.

Intervention groups

In the aromatherapy group, the researcher will pour a drop of oil on the non-absorbent tissue. First, we ask the patient to inhale the essence with 5 deep breaths, and then the non-absorbable tissue soaked in the essence at a distance of 10-15 cm from the patient's nose will attach to his clothes. In the thermotherapy group, we will place a hot water bag with temperature of 90-70 ° C, which is covered with a special towel, under the patient's shoulder for 20 minutes, and the people in the control group will receive routine care. In all 3 groups, before the intervention, the amount of shoulder pain will be evaluated using the Visual Analogue Scale. The patient is asked how much pain he has and then we perform the intervention and the amount of pain is measured and during discharge from recovery and one hour after discharge from the operating room the amount of pain will be evaluated.

Main outcome variables

patients' pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150715023216N9**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **prospective**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Said Amini Rarani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3522 6158

Email address

ghadami@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-10-12, 1400/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of heat therapy and aromatherapy with lavender essential oil on shoulder pain after laparoscopic cholecystectomy

Public title

The effect of heat therapy and aromatherapy on shoulder pain after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidate for cholecystectomy surgery by laparoscopic method Not having other pain focus Not having smelling problems No of usage perfumes and colognes Physicians' approval to ban from entering to research Not having known mental disorders Not using cigarettes and narcotic Non-diabetic patients

Exclusion criteria:

Nausea and vomiting in the patient Liver and kidney disorders Allergy to the essence of lavender Patient's intention to leave the intervention at any time Use of anticoagulant pregnancy Occurrence of medical emergencies conditions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, random sampling will be done and randomly selected individuals who have been admitted to the study, so that among all the people who have the criteria for entering the study according to the Random Digits Table is selected based on the sample size specified. Using 3 cards with letters A, B, C and placing them in sealed envelopes, the patient randomly selects one of them and is assigned to one of the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst is unaware of which group each sample belongs to

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University Of Medical Sciences

Street address

Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-07, 1400/05/16

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.071

Health conditions studied

1

Description of health condition studied

Cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description

Pain score in visual analogue scale

Timepoint

Before the intervention, after the intervention, the time of disease awareness in the Post-Anesthesia Care Unit, when discharge from the Post-Anesthesia Care Unit and one hour after discharge from the operating room

Method of measurement

Questionnaire visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: in the aromatherapy group with lavender essential oil, the researcher will pour a drop of oil on the non-absorbable napkin and attach it to the collar of the sample with a pin. We want him to inhale the scent for 2 minutes with 5 deep breaths and then attach the non-absorbable tissue soaked in essential oil, which will make the scent comfortable for at least an

hour, to the patient at a distance of 10-15 cm from the nose.

Category

Treatment - Drugs

2

Description

Intervention group 2: in the thermotherapy group, we will place a hot water bag with a temperature of 90-70 ° C, which is covered with a special towel, under the patient's shoulder for 20 minutes.

Category

Treatment - Devices

3

Description

Control group: Individuals in the control group receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Ahmad Ghadami

Street address

Hazar Jarib Street

City

esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

2

Recruitment center

Name of recruitment center

Ayatollah Kashani hospital

Full name of responsible person

Ahmad Ghadami

Street address

Ayatollah Kashani hospital, Kashani Street, Isfahan city, Isfahan province, iran

City

esfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

Kashani@mui.ac.ir

3

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Ahmad Ghadami

Street address

Amin Hospital, EbneSina st, Shohada Sq, Isfahan, Iran.

City

esfahan

Province

Isfahan

Postal code

8148653141

Phone

+98 31 3445 5051

Email

amin@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Hezar Jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 5226 1158

Fax

Email

ghadami@mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences, Hezar Jarib street

City

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Province

Isfahan

Postal code

8174673461

Phone

+98 31 5226 1158

Fax

Email

ghadami@mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Province

Isfahan

Postal code

8174673461

Phone

+98 31 5226 1158

Fax

Email

ghadami@mui.ac.ir

Web page address

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

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

Title and more details about the data/document

Individual participant data collected for the primary outcome measures

When the data will become available and for how long

After publication for one year

To whom data/document is available

For all people who request for data

Under which criteria data/document could be used

It is allowed to perform any analysis on the data, but use of data for publication is not allowed.

From where data/document is obtainable

Corresponding author of article

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

After requesting the data by email to corresponding author , the data will be sent after a maximum period of

one week
Comments