

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the effect of acupressural medicine and aromatherapy with peppermint essential oil on recovery quality of patients undergoing laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Comparison of the effectiveness of acupressure and peppermint essence on patient recovery quality under laparoscopic cholecystectomy surgery

##### Design

A randomized parallel clinical trial on 210 patients with laparoscopic cholecystectomy will be randomly divided into 3 groups in the form of 6 blocks with equal volume. random sequencing will be produced by sealed envelope software.

##### Settings and conduct

This study will be conducted in Besat Hospital in 1401 on 210 patients undergoing laparoscopic cholecystectomy. The sample sizes are divided into two groups intervention and one control group (each group 70 patients). In acupressure group the researcher with his thumb will press two minutes according to the rotational model of clockwise in the center of PC6, HT7, SP6. This will be done three times a day after surgery. In the second group, 3 drops of peppermint essential oil will be impregnated on a 2\*2 gas and will be attached to the patient's collar at a distance of 10 cm. Then we ask the patient to breathe normally for 5 minutes, this will be done three times a day after surgery. And the control group will receive routine care. The QoR-15 questionnaire will be completed day after surgery before the first intervention at 7:30 a.m. and the second day after surgery between 7 and 8 a.m.

##### Participants/inclusion and exclusion criteria

Inclusion; over 18 years, hospitalization at least one day after surgery, having patient's consent, no alcohol and cigarette exclusion; carpal tunnel, olfactory system disorder, scars at HT7, PC6, SP6, use of herbal medicines two weeks ago surgery, allergies to plants, neurological disease, physical disability

##### Intervention groups

The control group receives routine care, acupressural

medicine and peppermint essential oil group, in addition to routine care, receive the intervention three times a day after surgery.

##### Main outcome variables

quality of recovery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220515054852N1**

Registration date: **2022-05-25, 1401/03/04**

Registration timing: **prospective**

Last update: **2022-05-25, 1401/03/04**

Update count: **0**

##### Registration date

2022-05-25, 1401/03/04

##### Registrant information

##### Name

Fatemeh Zare

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1014

##### Email address

fatemeh.zarea228@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of acupressural medicine and aromatherapy with peppermint essential oil on recovery quality of patients undergoing laparoscopic cholecystectomy

**Public title**

Comparison of the effect of acupressural medicine and aromatherapy with peppermint essential oil on recovery quality of patients undergoing laparoscopic cholecystectomy

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ages over 18 Hospitalization at least one day after surgery Having patient's consent to participate in the research No alcohol or cigarettes

**Exclusion criteria:**

Carpal Tunnel Syndrome Olfactory system disruption Having scars at HT7-PC6 and SP6 points Use of herbal medicines two weeks ago surgery Allergies to plants and respiratory disorders History of Neurological Disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **210**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method will be randomized into 3 groups in the form of 6 blocks with equal volume. Block randomization method is a common method to ensure that during the random division process, the number of people is distributed equally among the study groups. Random splitting is done in the form of blocks with predetermined size. Random sequencing will be produced by blocking method by sealed envelope software. In this software, the total sample size and the number of groups are entered into the software. The randomization unit in the mentioned software is the individual. The output of the software is a grouped list that distributes the number of samples randomly into three groups. According to the list, the time of referral will be distributed in three groups to reach the required number in each group

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2022-05-08, 1401/02/18

**Ethics committee reference number**

IR.UMSHA.REC.1401.136

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

laparoscopic cholecystectomy

**ICD-10 code**

K80.1

**ICD-10 code description**

Calculus of gallbladder with other cholecystitis

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

quality of recovery

**Timepoint**

First and second day after surgery

**Method of measurement**

QoR-15 questionnaire

**Secondary outcomes**

empty

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

Intervention group 1: In addition to receiving routine hospital care, the researcher with his thumb, according to the rotational model of the clock at the PC6 point, will press two minutes and take a minute off, likewise at the HT7 point two minutes of acupressure and one minute rest, then at the SP6 point two minutes of pressure will be done unilaterally. This will be done three times a day after surgery for patients.

**Category**

Treatment - Other

**2**

**Description**

Intervention group 2: In the second group, in addition to receiving routine care, 3 drops of peppermint essential oil will be impregnated on a 2\*2 gas and will be attached to the patient's collar at a distance of 10 cm from the patient's nose. Then we ask the patient to breathe normally for 5 minutes, this will be done three times a day after surgery.

**Category**

Treatment - Other

**3**

**Description**

Control group: The control group will receive routine hospital care that is the same for patients

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Rasoul Salimi

**Street address**

Hokama Ave

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**Postal code**

4541165148

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+98 81 3264 0036

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Besat@umsha.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Shahid Fahmideh Ave

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**Phone**

+98 81 3838 0717

**Email**

m\_research@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Zare

**Position**

Msc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Surgical technologist student

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**Phone**

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**Email**

fatemeh.zarea228@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Behzad Imani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All individual data is shared after people are identifiable.

Includes demographic data and recovery quality data

**When the data will become available and for how long**

Data is shared three months after the results are printed

**To whom data/document is available**

All researchers can apply for data

**Under which criteria data/document could be used**

The data is provided that they first have a clear purpose to use the data. Secondly, wherever this data is supposed to be used, the primary source of the data is mentioned

**From where data/document is obtainable**

To receive data, you can refer to the following e-mail address. fatemeh.zarea228@gmail.com

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

After submitting the request at the e-mail address, the data will be sent over time.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Zare

**Position**

Msc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

surgical technologist student

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