Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 sealedenvelope 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 sealedenvelope 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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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

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Shahid Fahmideh Ave

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Behzad Imani
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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