

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of acupressure in several points on pain and physiological parameters of patients undergoing laparoscopic cholecystectomy surgery

Protocol summary

Study aim

Determining the effect of acupressure in several points on pain and physiological parameters of patients undergoing laparoscopic cholecystectomy surgery

Design

In this clinical trial, 92 patients who are candidates for laparoscopic cholecystectomy are randomly selected. Participants are randomly based on a Random Digital Table divided into intervention and control group with parallel and double-blinded groups.

Settings and conduct

The place of intervention is in the operating room of Al-Zahra hospitals in Isfahan, The research is double-blind, where the statistical analyst and the outcome evaluator do not know about the study groups.

Participants/Inclusion and exclusion criteria

inclusion criteria: candidates for laparoscopic cholecystectomy surgery. Exclusion criteria: Drug and alcohol addiction; patient's intention to leave the intervention at any time.

Intervention groups

In the intervention group, 30 minutes before the surgery, two acupressure steps will be performed on the patient with an interval of 20 minutes. In order to intervene, pressure points K1, H7, P6, LI4, LI11, SJ5 are pressed. Then, at the Post-Anesthesia Care Unit, and after ensuring the patient's consciousness, the intervention will be performed every 20 minutes up to 9 times on points K1, H7, P6, LI4, LI11, SJ5 respectively, and the participant in the control group will receive routine care. shoulder pain using a Visual Pain Scale and hemodynamic information including heart rate, systolic and diastolic blood pressure, breathing rate and heart rate is measured and recorded.

Main outcome variables

patients' pain; blood pressure; heart rate; respiratory rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150715023216N14**

Registration date: **2023-01-22, 1401/11/02**

Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**

Update count: **0**

Registration date

2023-01-22, 1401/11/02

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

2023-02-04, 1401/11/15

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure in several points on pain and physiological parameters of patients undergoing laparoscopic cholecystectomy surgery

Public title

The effect acupressure on pain and physiological parameters of patients laparoscopic cholecystectomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients undergoing laparoscopic cholecystectomy surgery Informed consent to participate in the study Healthy upper limbs and metatarsus

Exclusion criteria:

Suffering from vascular, inflammatory, diabetes and neuropsychological diseases Other recent surgeries or traumas Suffering from sensory-motor disorders Drug and alcohol addiction Performing acupressure or other complementary medicine techniques within the past two weeks

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

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 2 cards with letters A, B 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)

Double blinded

Blinding description

The statistical analyst is unaware of which group each sample belongs to. In addition, a research associate is used to evaluate the outcome.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical University of Isfahan

Street address

Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746/73461

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.140

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 surgery, when the patient is awake in the Post-Anesthesia Care Unit, 72 hours after the surgery

Method of measurement

Questionnaire visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, pressure points K1, H7, P6, LI4, LI11, SJ5 are subjected to acupressure 30 minutes before the start of surgery, with an interval of 20 minutes. Then, at the Post-Anesthesia Care Unit, and after ensuring the patient's consciousness, the intervention will be performed on points K1, H7, P6, LI4, LI11, SJ5, respectively, every 20 minutes.

Category

Prevention

2

Description

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

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Saeid Amini Rarani

Street address

Hazar Jarib Street

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8174675731

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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamraza Askari

Street address

Hezarjerib Street, Isfahan, Iran

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8174673461

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askari@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

Saeid Amini Rarani

Position

Academic member

Latest degree

Master

Other areas of specialty/work

Nursery

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Full name of responsible person

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Position

Academic member

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

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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