

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparative Study of the Effect of Acupressure and Transcutaneous Electric Acupoint Stimulation on Severity of Pain, Nausea and Vomiting, Hypothermia and Hemodynamic Status after Laparoscopic cholecystectomy patients

Protocol summary

Study aim

Comparison of the effect of acupressure and electrical skin stimulation on pain intensity, nausea and vomiting, hypothermia and hemodynamic status after laparoscopic cholecystectomy

Design

This study will be performed on 114 patients (male / female) candidates undergoing laparoscopic cholecystectomy who meet the inclusion criteria in the operating room of Al-Zahra Hospital in Isfahan in 2020. And were randomly divided into three groups: 1 control group and 2 intervention groups.

Settings and conduct

The researcher and the participant have been blinded. The study in Alzahra Hospital of Isfahan on laparoscopic cholecystectomy patients under general anesthesia was performed in 2020 and includes three groups of acupressure at pc6 point and electrical stimulation of this point with tens device and control group.

Participants/Inclusion and exclusion criteria

Entry requirements: The patient's willingness and satisfaction to participate in the intervention. The patient is fully conscious. The target organ should not have an anatomical problem in terms of performing acupressure and Acupressure-Trans Electrical nerve Stimulation (Acu-Tens) at PC6 point(One of the points in acupuncture in Acupuncture). All patients underwent general anesthesia with the same medication. Patients are between 30-60 years old Do not have neurological or psychiatric illnesses (according to the patient) or a specific illness Be in ASA I, II category. No entry conditions: History of acute and chronic nausea and vomiting (such as gastrointestinal and ear disorders) ,Drug and alcohol addiction, History of using acupressure

Intervention groups

The control group includes participants who are not

interfered with. The intervention group with acupressure includes participants who are applied acupressure at the designated pc6 point. Another intervention group includes people who are electrically stimulated at this point on the pc6 using a tens device

Main outcome variables

Pain, nausea, vomiting, chills, hemodynamic status, acupressure, electrical stimulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200804048300N1**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Maryam Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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hrm6871@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-25, 1399/06/04

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of the Effect of Acupressure and Transcutaneous Electric Acupoint Stimulation on Severity of Pain, Nausea and Vomiting, Hypothermia and Hemodynamic Status after Laparoscopic cholecystectomy patients

Public title

Comparison of the effect of acupressure and electrical stimulation in acupressure points on postoperative complications

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's willingness and satisfaction to participate in the intervention The patient is fully conscious The target organ should not have an anatomical problem in terms of performing acupressure and Acupressure-Trans cutaneous Electrical Nerve Stimulation(Acu-Tens) at PC6(One of the points in acupuncture) point All patients underwent general anesthesia with the same medication Patients are between 30-60 years old Do not have neurological or psychiatric illnesses (according to the patient) or a specific illness Be in ASA I, II category

Exclusion criteria:

History of acute and chronic nausea and vomiting (such as gastrointestinal and ear disorders) Drug and alcohol addiction History of using acupressure

AgeFrom **30 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **114****Randomization (investigator's opinion)**

Randomized

Randomization description

Permutation block randomization will be used to assign groups. Patients participating in the study were divided into 3 groups of 38 using 6 blocks using the letters AA, CC, TT (for group parity). For permutation block randomization, the method of sealed envelopes, random sequence will be used.

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 Mazandaran University of Medical Sciences

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No.1, 41Alley, kashani Ave

City

esfahan

Province

Isfahan

Postal code

8137946855

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.MAZUMS.REC.1399.154

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

Laparoscopic cholecystectomy patients

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

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

Pain intensity

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

based on visual analog scale

2**Description**

nausea intensity

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

based on visual analog scale

3

Description

The rate of vomiting

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

Based on the number of times according to previous studies

4

Description

Hypothermia

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

Measurement of central body temperature using tympanic thermometer (TH839)

5

Description

Number of breaths

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

Using patient monitoring of vital signs

6

Description

Pulse count

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

Using patient monitoring of vital signs

7

Description

Systolic and diastolic blood pressure

Timepoint

before surgery, at the beginning of recovery, 2, 4, 6, 24 and 48 hours after surgery

Method of measurement

Using patient monitoring of vital signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: In the acupuncture group, using a special acupuncture bracelet with the brand name PsiBand with American design and made in China during the entire recovery period of the patient in the postoperative care ward, on pc6 point which is already located by the researcher It is marked to be closed, and by applying the necessary pressure by this bracelet, the necessary items are recorded at this point.

Category

Prevention

2

Description

Intervention group 2: In the Acu-tens group of STIMULATOR 710P PULS with Frequency = 2-5 HZ and Duration = Wider Pulses (200-250ms) Pulse by placing electrodes at pc6 point on the forearm of both hands with the intensity that the patient feels Moore Moore It gets in the hand but it does not bother him, it is used for 30 to 45 minutes to stimulate this point

Category

Prevention

3

Description

Control group: 38 patients in the control group will routinely receive routine operating room care, including medication, during and after surgery and will not receive any special intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

AL zahra hospital

Full name of responsible person

Ebrahim Nasiri Formi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saeedi

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No. 140, Amir Mazandarani Ave., Keshavarzi Blwd.

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Maryam Nazari

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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student

Latest degree

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Other areas of specialty/work

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Fax**Email**

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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