Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Compartive 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)

Phone

+98 31 3365 1645

Email address

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
Compartive 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
Age
From **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
Street address
No.1, 41Alley, kashani Ave
City
esfahan
Province
Isfehan
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 acupressure group, using a special acupressure 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
Street address
Sofe.Ave sofe Blvd
City
Esfahan
Province
Isfehan
Postal code
8137946855
Phone
+98 31 3365 1645
Email
hrm6871@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid saeedi
Street address
No. 140,Amir Mazandarani Ave., Keshavarzi Blwd.
City
sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4850
Email
majsaeedi@yahoo.com

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
Anesthesiology
Street address
No.1,41 Alley, Kashani Ave
City
Esfahan
Province
Isfehan
Postal code
8137946855
Phone
+98 31 3365 1645
Fax
Email
hrm6871@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ebrahim Nasiri Formi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Mazandaran University of Medical Sciences, Farahabad Ave.
City
Sari
Province
Mazandaran
Postal code
8137946855
Phone
+98 11 3304 4000
Email
Ebrahim.Nasiri.f@gmail.com

Person responsible for updating data

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
Anesthesiology
Street address
No.1,41 Alley, Kashani Ave
City
Esfahan
Province
Isfehan
Postal code
8137946855
Phone
+98 31 3365 1645
Fax
Email
hrm6871@gmail.com

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