

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of acupuncture on hemodynamic stability and postoperative nausea and pain in laparoscopic cholecystectomy

Protocol summary

Study aim

To determine the effect of acupuncture on hemodynamic stability and postoperative nausea and pain in laparoscopic cholecystectomy

Design

A randomized, double blinded clinical trial with two arm parallel groups

Settings and conduct

The patients are receiving fentanyl, midazolam and lidocaine and then propofol and atracurium as induction and maintained by propofol. Needles are inserted on 5 acupoints LI4, P6, GB34, Liv2, St36 after intubation and will be maintained for 20 minutes after the acupuncture. The mean arterial pressure and the heart rate will be measured before induction, 2 minutes after intubation, immediately before and 5, 30, 60, 90 and 120 minutes after gas insufflation. The severity of pain and nausea and incidence of vomiting will be evaluated respectively by NRS and likert scale and by asking the patient after surgery in the post operative care unit and 6 hours later. Considering the participants are unconscious before needling so they are blinded. Data collector and outcome assessor are also blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates of laparoscopic cholecystectomy Exclusion criteria: Being pregnant , Past medical history of hypertension , No access to acupuncture points

Intervention groups

The patients considered for laparoscopic cholecystectomy who are older than 18 and not pregnant are included in our research. Needles are going to be inserted after induction and intubation. The mean arterial pressure (MAP) and the heart rates (HR) of the patient will be measured during the surgery. The evaluation of the severity of pain and nausea and the incidence of vomiting will be after the surgery. the method of anesthesia and the variables in the control group, who are not being needled, are same as the interventional

group.

Main outcome variables

Mean arterial pressure; Heart rate variability; Pain; Nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101026005026N11**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name

Masood Mohseni

Name of organization / entity

Rasul Akram hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2326

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-23, 1398/09/02

Expected recruitment end date

2020-06-22, 1399/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupuncture on hemodynamic stability and postoperative nausea and pain in laparoscopic cholecystectomy

Public title

The effect of acupuncture on hemodynamic stability and postoperative nausea and pain in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates of laparoscopic cholecystectomy

Exclusion criteria:

Being pregnant Past medical history of hypertension No access to acupuncture points

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **25****Randomization (investigator's opinion)**

Randomized

Randomization description

Random number generator on calculator Random numbers will be generated on a calculator. If the generated number is even, it will be allocated to the interventional group. Otherwise, it will be allocated to the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be informed about possibility of receiving acupuncture on the identified acupoints before receiving anesthesia. Considering the participants are unconscious, they are not aware of being in interventional or control group. Data collector and outcome assessor are blinded to the fact that patients have received acupuncture or not.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.IUMS.FMD.REC.1398.342

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

pain after laparoscopic cholecystectomy

ICD-10 code

R52.0

ICD-10 code description

Acute pain

2**Description of health condition studied**

nausea and vomiting after laparoscopic cholecystectomy

ICD-10 code

R11

ICD-10 code description

nausea and vomiting

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

Mean arterial pressure variability

Timepoint

Before induction of anesthesia, 2 minutes after intubation, immediately before and 5, 30, 60, 90 and 120 minutes after gas insufflation for laparoscopic cholecystectomy

Method of measurement

non invasive Blood pressure monitoring

2**Description**

Heart rate variability
Timepoint
Before induction of anesthesia, 2 minutes after intubation, immediately before and 5, 30, 60, 90 and 120 minutes after gas insufflation for laparoscopic cholecystectomy
Method of measurement
Heart rate monitoring

Secondary outcomes

1

Description
pain
Timepoint
to determine the severity of pain after laparoscopic cholecystectomy in recovery room and 6 hours later in the ward
Method of measurement
Numerical rating scale

2

Description
nausea
Timepoint
to determine the severity of nausea after laparoscopic cholecystectomy in recovery room and 6 hours later in the ward
Method of measurement
likert scale

Intervention groups

1

Description
Intervention group: Acupuncture for 20 minutes at LI4, P6, GB34, Liv2, St36
Category
Treatment - Other

2

Description
Control group: There was no acupuncture
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Masood Mohseni
Street address
Niaysh Ave., Sattar Khan St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Masood Mohseni
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Undecided - It is not yet known if there will be 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

IPD collected for the primary and secondary outcomes

When the data will become available and for how long

Immediately after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

The result of further analysis may not be presented to public without permission

From where data/document is obtainable

Masood.mohseni@gmail.com

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

A reasonable request from an academic source will be responded within 10 working days

Comments