

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

mohseni@med.mui.ac.ir

##### 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

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1458843337

##### Phone

+98 21 6435 2326

##### Email

Masood.mohseni@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Abbas Motevalian

##### Street address

Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

##### Phone

+98 21 8670 2503

##### 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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Rasul Akram hospital, Niayesh Ave, Sattarkhan St

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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Specialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Sharareh Barband

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Email**

sharareh.barband@gmail.com

## 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**