Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 cholecyctectomy 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)

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+98 21 6435 2326

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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
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

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Niaysh Ave., Sattar khan St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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 futher 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 resonable request from an academic source will be responded within 10 working days
Comments