Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of skin electrical stimulation at acupuncture points PC6, ST36 and LI4 on hemodynamics, pain, nausea and vomiting during anesthesia in patients requiring elective laparoscopic cholecystectomy

Protocol summary

Study aim
Determining the effects of electrical skin stimulation at acupuncture points PC6, ST36 and LI4 on hemodynamics, pain, nausea and vomiting during general anesthesia in patients requiring elective laparoscopic cholecystectomy

Design
This study is a double - blind randomized clinical trial in phase 3 with two groups of control and intervention that will be conducted on 70 patients need general anesthesia. Random allocation will be done using random letters and computer software.

Settings and conduct
The study is conducted on elective patients who are candidates for general anesthesia in teaching hospitals in Kermanshah. In the intervention group, active electrical stimulation is performed on acupuncture points during the patient's anesthesia. In the control group, electrical stimulation is not performed. Patients and the researcher recording the data are unaware of the grouping and type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who need surgery for cholecystectomy and general anesthesia; reading and writing literacy; verbal ability and healthy vision; healthy skin healthy. Exclusion criteria: history of smoking and opioids؛ use of analgesics and antiemetic drugs during the past 24 hours; history of diabetes and cardiovascular disease; having a pacemaker.

Intervention groups
In the control group (C), during anesthesia, electrodes are connected bilaterally to acupuncture points in the PC6, ST36, and LI4 areas of the patients, but the stimulation device is inactive and turned off. In the intervention group (I), bilateral electrical stimulation at the aforementioned acupuncture points continues simultaneously from 10 minutes before anesthesia induction until the end of anesthesia and recovery.

Main outcome variables
Blood pressure changes; heart rate changes; pain intensity; amount of analgesia taken; severity of nausea and vomiting

General information

Reason for update
Updating study start and end dates

Acronym

IRCT registration information
IRCT registration number: **IRCT20240123060780N4**
Registration date: **2026-03-16, 1404/12/25**
Registration timing: **prospective**

Last update: **2026-07-05, 1405/04/14**
Update count: **1**

Registration date
2026-03-16, 1404/12/25

Registrant information

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Rasoul Kavyannejad

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-21, 1405/01/01

Expected recruitment end date
2026-07-23, 1405/05/01

Actual recruitment start date
2026-03-22, 1405/01/02
Actual recruitment end date
2026-06-22, 1405/04/01
Trial completion date
2026-06-23, 1405/04/02

Scientific title
Effects of skin electrical stimulation at acupuncture points PC6, ST36 and LI4 on hemodynamics, pain, nausea and vomiting during anesthesia in patients requiring elective laparoscopic cholecystectomy

Public title
Effects of skin electrical stimulation at acupuncture points on hemodynamics, pain, nausea and vomiting during anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female patients requiring elective laparoscopic cholecystectomy who have anesthesia risk levels 1 and 2 according to the American Society of Anesthesiologists (ASA) classification Reading literacy Healthy speech and vision abilities The skin in the area of electrical stimulation be healthy
Exclusion criteria:
Peripheral edema in the area of stimulation History of smoking or drug use Use of analgesic or anti-nausea and vomiting medications in the past 24 hours The patient's previous complicated surgical and anesthetic history at the time of the history taking. Pregnancy Breastfeeding Taking sedatives History of diabetes History of vascular disease Having pacemakers and implantable cardiac defibrillators
Age
From **25 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of samples in this study is done by the Randomization Main computer software. Given the presence of two groups, a random sequence of the letters I and C is created in blocks with a random number of 2 letters. Each letter symbolizes one of the study groups. Then these blocks are placed in sealed envelopes. One of the blinded researchers opens one of the envelopes before the start of the study and finally the patient is placed in one of the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the control group (C); the electrodes of the electrical stimulation device are placed at the acupuncture points, but the stimulation device is inactive. In the intervention group (I); the stimulation electrodes are placed at the acupuncture points and connected to the electrical stimulation device with active function. Due to the identical apparent interventions and the patient's lack of knowledge of the stimulation group and intervention, the patients were blinded to the intervention. In the control group, the stimulation device is turned off and no real stimulation is applied. Given that the patients in the intervention group may feel the stimulation, the current threshold level is considered minimal. In addition, most of the stimulation period occurs during the patient's anesthesia and the patient is not conscious and alert. Electrical stimulation is performed by one study colleague and the recording of study variables is performed by another study colleague who was blinded to the grouping. Therefore, two study assistants are observed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
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No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard
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Postal code
6715847141
Approval date
2026-02-22, 1404/12/03
Ethics committee reference number
IR.KUMS.MED.REC.1404.266

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89.1

ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
Heart rate
Timepoint
Heart rate is measured before and after laryngoscopy (insertion of the endotracheal tube), before and after removal of the endotracheal tube, and every 15 minutes during anesthesia.
Method of measurement
Using patient-attached monitoring

2

Description
Systolic and diastolic blood pressure
Timepoint
Blood pressure is measured before and after laryngoscopy (insertion of the endotracheal tube), before and after removal of the endotracheal tube, and every 15 minutes during anesthesia.
Method of measurement
Using patient-attached monitoring

Secondary outcomes

1

Description
Pain
Timepoint
Postoperative pain levels are measured in the recovery area and at 6, 12, and 24 hours after the operation.
Method of measurement
Based on the Visual Analog Scale (VAS)

2

Description
Severity of postoperative nausea and vomiting
Timepoint
Within 24 hours after surgery
Method of measurement
Using the Simplified PONV Impact Scale

3

Description
Opioid analgesic dosage
Timepoint
Within 24 hours after surgery
Method of measurement
Dosage in milligrams based on the patient's record

4

Description
Bispectral Index (BIS)
Timepoint
Before induction of anesthesia, before and after laryngoscopy, every 15 minutes during anesthesia, and before and after tracheal extubation.
Method of measurement
Measured using a patient-attached bispectral index (BIS) monitor.

Intervention groups

1

Description
Intervention group: Stimulation electrodes are placed bilaterally at the Hugo (LI4), Niguan (PC6), and Zusanli (ST36) acupuncture points and connected to an active electrical stimulation device. The current is set to 5 mA for the upper limb and 10 mA for the lower limb with a frequency of 100 Hz.
Category
Treatment - Devices

2

Description
Control group: Stimulation electrodes are placed bilaterally at the Hugo (LI4), Niguan (PC6), and Zusanli (ST36) acupuncture points and connected to an electrical stimulation device with passive function.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
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3

Recruitment center

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Sponsors / Funding sources

1

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Javad Aminisaman

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available