# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the Effects of Preoperative Electroacupuncture and Acupuncture on Postoperative Nausea and Vomiting in Patients Undergoing Hysterectomy: A Triple-Blind, Randomized Clinical Trial

## Protocol summary


**Study aim**
The objective of this study is to evaluate and compare the effects of preoperative electroacupuncture and acupuncture on postoperative nausea and vomiting after hysterectomy

**Design**
This will be a randomized, triple-blind, parallel-group clinical trial with 90 participants. Randomization will use variable block sizes generated by software.

**Settings and conduct**
The study will be conducted at Bahar Hospital, Shahroud

**Participants/Inclusion and exclusion criteria**
Women aged 18–60 years, ASA class I–II, BMI 20–30, non-smokers, and candidates for hysterectomy under general anesthesia will be included. Pregnancy, psychiatric disorders, chronic pain, recent antiemetic or steroid use, pacemaker, insertion-site infection, and surgery >3 hours will be exclusion criteria

**Intervention groups**
Participants will be assigned to one of three groups: electroacupuncture, traditional acupuncture, or sham treatment administered preoperatively.

**Main outcome variables**
Incidence of postoperative nausea and vomiting at 4, 8, 12, and 24 hours; Nausea severity using a 100-mm VAS at the same time points; Use of antiemetic medications during 0–4, 4–8, 8–12, and 12–24 hours postoperatively


## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20200206046395N7**
Registration date: **2025-11-22, 1404/09/01**
Registration timing: **prospective**
Last update: **2025-11-22, 1404/09/01**
Update count: **0**

**Registration date**
2025-11-22, 1404/09/01


**Registrant information**
**Name**
Mobin Mottahedi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 23 3233 8090
**Email address**
mobinmottahedi1372@gmail.com


**Recruitment status**
**recruiting**
**Funding source**

**Expected recruitment start date**
2025-12-06, 1404/09/15
**Expected recruitment end date**
2026-12-06, 1405/09/15
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the Effects of Preoperative Electroacupuncture and Acupuncture on Postoperative Nausea and Vomiting in Patients Undergoing Hysterectomy: A Triple-Blind, Randomized Clinical Trial

**Public title**
The Effect of Preoperative Electroacupuncture and Acupuncture on Post-Hysterectomy Nausea and Vomiting

**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Women aged 18 to 60 years American Society of Anesthesiologists (ASA) physical status class I or II Body mass index (BMI) between 20 and 30 Non-smokers Candidates for hysterectomy under general anesthesia No history of nausea or vomiting within 24 hours prior to surgery
**Exclusion criteria:**
Pregnancy or breastfeeding Psychiatric disorders or substance abuse (self-reported) Chronic pain syndromes Self-medication with antiemetics, opioids, or corticosteroids within 3 days before surgery Presence of a cardiac pacemaker Infection at the needle insertion site Surgery duration exceeding 3 hours
**Age**
From **18 years** old to **60 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **126**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization was performed using block randomization with variable block sizes to ensure balanced allocation across the three study groups. The random sequence was generated by an independent individual who was not involved in patient recruitment or intervention administration, using Random Allocation Software. Participant assignment was implemented through sequentially numbered, opaque, sealed envelopes (SNOSE). After confirming eligibility, the responsible researcher opened the next envelope in sequence to determine the participant’s group allocation. This method ensured proper randomization and allocation concealment.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
In this study, participants, the principal investigator (except for the individual who will administer the intervention), clinical staff including physicians, anesthesiologists and nurses, as well as outcome assessors and data analysts will all be kept blinded to group allocation. The intervention will be administered in a separate room by an independent individual who will be the only person aware of the assignments and will have no role in data collection, clinical care or data analysis. The appearance of the device and the needle placement procedures will be standardized across all three groups to prevent participants from identifying their assigned intervention. Clinical staff will not be informed of group assignments at any stage of patient care. Outcome data will be collected by a trained nurse who will record information solely based on participant codes and will remain unaware of group allocation. The data analyst will receive anonymized coded data and will remain blinded until all analyses are completed. Group identities will only be revealed after the final analysis by the independent individual
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of Shahroud University of Medical Sciences
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Approval date**
2025-11-15, 1404/08/24
**Ethics committee reference number**
IR.SHMU.REC.1404.112

## Health conditions studied

### 1

**Description of health condition studied**
Postoperative nausea and vomiting
**ICD-10 code**
K91.0
**ICD-10 code description**
Vomiting following gastrointestinal surgery

## Primary outcomes

### 1

**Description**
The Prevalence of Postoperative Nausea and Vomiting (PONV)
**Timepoint**
At 4, 8, 12, and 24 hours after surgery.
**Method of measurement**

Direct questioning of patients using the following questions:'Did you feel nauseous at any time since your last visit?''Did you vomit during this period?

**2**

**Description**
Nausea Severity
**Timepoint**
It will be evaluated and documented at 4, 8, 12, and 24 hours after surgery.
**Method of measurement**
Assessment using a 100-millimeter Visual Analogue Scale where patients mark their symptom intensity on a straight line.

**3**

**Description**
Need for Postoperative Antiemetic Drugs
**Timepoint**
0–4 hours, 4–8 hours, 8–12 hours, and 12–24 hours after surgery
**Method of measurement**
Counting the number of patients who received antiemetic drugs and their dosage.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention Group 1 (Manual Acupuncture) Participants in this group will receive manual acupuncture at the standard PC6 (Neiguan) and ST36 (Zusanli) points. The PC6 point is located approximately 2 cm (about 3 fingerbreadths) proximal to the wrist crease on the inner forearm. The ST36 point is located 3 cm (about 4 fingerbreadths) below the lower border of the patella and one fingerbreadth lateral to the anterior crest of the tibia. After skin disinfection, stainless steel needles (0.30 × 40 mm) will be inserted into these points until the patient reports a De Qi sensation (heaviness, pressure, or mild tingling). The needles will be retained for 30 minutes prior to surgery without any electrical stimulation.
**Category**
Rehabilitation

**2**

**Description**
Intervention Group 2 (Electroacupuncture) Participants in this group will receive electroacupuncture. Needle insertion at the standard PC6 and ST36 points will be performed identically to the Manual Acupuncture group. Following needle insertion and the elicitation of De Qi, electrodes from an XS-998B electroacupuncture device will be connected between the PC6 and ST36 points. Variable frequency electrical stimulation (20-100 Hz) will be applied for 30 minutes prior to surgery. The current intensity will be adjusted to a level perceived as strong but not painful by the patient.
**Category**
Rehabilitation

**3**

**Description**
Control Group (Sham Acupuncture) Participants in the control group will receive sham acupuncture. Non-penetrating, placebo needles will be placed superficially at non-specific points located approximately 2 cm away from the standard PC6 (Neiguan) and ST36 (Zusanli) acupuncture points. The needles will be inserted superficially without deep insertion or any form of stimulation (manual or electrical) and will remain in place for 30 minutes prior to surgery. This procedure is designed to mimic the psychological aspect of the intervention without producing a specific physiological effect.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Bahar Hospital of Shahroud
**Full name of responsible person**
Mobin Mottahedi
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Phone**
+98 910 038 8406
**Email**
Mobinmottahedi1372@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Hossein Ebrahimi
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud

**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Phone**
+98 912 373 1317
**Email**
ebrahimi@shmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Shahroud 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**
Shahroud University of Medical Sciences
**Full name of responsible person**
Mobin Mottahedi
**Position**
Instructor
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Phone**
+98 23 3233 8090
**Email**
Mobinmottahedi1372@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Mobin Mottahedi
**Position**
Instructor
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Phone**
+98 23 3233 8090
**Email**
mobinmottahedi1372@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Mobin Mottahedi
**Position**
Instructor
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
7th Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۵۵
**Phone**
+98 23 3233 8090
**Email**
mobinmottahedi1372@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**
A final decision regarding the sharing of individual participant data has not been made at this time. This matter requires further consideration of ethical issues, data confidentiality, and relevant regulations. The final decision will be made after consultation with the ethics committee and relevant stakeholders.

**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