

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effects of compression bracelet and compression sticker at p6 on patients' physiological indices and postoperative nausea and vomiting prevention in laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Comparison of the effects of compression bracelet and compression sticker at p6 on patients' physiological indices and postoperative nausea and vomiting prevention in laparoscopic cholecystectomy

##### Design

Clinical trial with control group, Randomized, with parallel groups, single blind

##### Settings and conduct

The aim of this study was to determine the prevalence of postoperative nausea and vomiting in the medical centers of Hamadan using a bracelet and a tag in patients in the study groups. It should be noted that by removing the metal button on the bracelet as well as the pressure tag, the blinding is done in the sampling phase.

##### Participants/Inclusion and exclusion criteria

Patient Entry Conditions: Patients Candidate for Laparoscopic Cholecystectomy with General Anesthesia  
Age over 18 years P6 skin health No nausea for any reason before entering the study No visual impairment to diagnose VAS No angiocut at point P6 And exclusion criteria include: The patient is discharged before the end of the study Patient dissatisfaction to continue the study Sensitivity to acupuncture bracelet and label Bleeding and any factors that lead to open surgery

##### Intervention groups

The grop of P6 acupressure bracelet The grop of P6 acupressure sticker Control group without any intervention

##### Main outcome variables

Prevention of nausea and vomiting; Hemodynamic stability

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190915044770N1**

Registration date: **2019-10-25, 1398/08/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-25, 1398/08/03**

Update count: **0**

#### Registration date

2019-10-25, 1398/08/03

#### Registrant information

##### Name

Asghar Farahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3822 4894

##### Email address

asghar.farahani@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-10-23, 1398/08/01

#### Expected recruitment end date

2020-01-21, 1398/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effects of compression bracelet and compression sticker at p6 on patients' physiological

indices and postoperative nausea and vomiting prevention in laparoscopic cholecystectomy

#### Public title

The effect of pressure bracelet and pressure sticker on nausea and vomiting

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Candidate for Laparoscopic Cholecystectomy with General Anesthesia Age over 18 years Having skin health at P6 No nausea for any reason before entering the study No visual impairment to diagnose VAS No angiocut at point P6

##### Exclusion criteria:

The patient is discharged before the end of the study Patient dissatisfaction to continue the study Sensitivity to acupuncture bracelet and acupressure sticker Bleeding and any factors that lead to open surgery

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **175**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Patients in this study were blinded to pressure bracelet and pressure tag groups in the intervention and control groups. They are not aware of the type of bracelet (with or without a push button) and a push sticker (with or without a metal piece) that both instruments have a complete similarity to each other.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Hamadan university of medical sciences

###### Street address

Shahid Fahmideh BLVD

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838698

##### Approval date

2019-08-10, 1398/05/19

##### Ethics committee reference number

IR.UMSHA.REC.1398.428

### Health conditions studied

#### 1

##### Description of health condition studied

Cholecystectomy

##### ICD-10 code

K91.86

##### ICD-10 code description

Retained Cholelithiasis following Cholecystectomy

### Primary outcomes

#### 1

##### Description

Prevention of nausea

##### Timepoint

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

##### Method of measurement

Visual Analogue Scale

#### 2

##### Description

Beating

##### Timepoint

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

##### Method of measurement

Find abundance with checklists

#### 3

##### Description

Vomiting

##### Timepoint

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

##### Method of measurement

Find abundance with checklists

#### 4

##### Description

Pain

##### Timepoint

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Visual Analogue Scale

**5****Description**

The amount of anti-nausea and vomiting medication

**Timepoint**

24 hours after surgery

**Method of measurement**

Check list

**6****Description**

Blood pressure measurement

**Timepoint**

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Handheld pressure gauge

**7****Description**

The number of pulses per minute

**Timepoint**

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Cardiac monitoring device

**8****Description**

Breath rate per minute

**Timepoint**

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Visual observation

**9****Description**

Body temperature

**Timepoint**

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Mercury thermometer

**10****Description**

Arterial Oxygen Saturation Percentage

**Timepoint**

Immediately after the patient is fully awake, 1, 6 and 24 hours after surgery

**Method of measurement**

Cardiovascular monitoring

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Group with pressure bracelet at point P6. After selecting the appropriate wristband, the researcher closed the patient's wrist one hour before starting anesthesia on the P6 point and held it for 6 hours after embedding and then removing it. It should be noted that the severity of nausea based on the VAS visual scale, the severity of pain based on the visual VAS scale, the frequency of vomiting based on the checklist, as well as vital symptoms including respiratory rate, heart rate, blood pressure and temperature They are measured at times immediately after full consciousness in recovery, one hour later, 6 hours later, and 24 hours after surgery. The checklist will also be assessed 24 hours after surgery.

**Category**

Prevention

**2****Description**

Intervention group: group with pressure sticker at point P6. After selecting the appropriate sticker, the researcher closed the patient's sticker one hour before starting anesthesia on the P6 point and held it for 6 hours after embedding and then removing it. It should be noted that the severity of nausea based on the VAS visual scale, the severity of pain based on the visual VAS scale, the frequency of vomiting based on the checklist, as well as vital symptoms including respiratory rate, heart rate, blood pressure and temperature They are measured at times immediately after full consciousness in recovery, one hour later, 6 hours later, and 24 hours after surgery. The checklist will also be assessed 24 hours after surgery.

**Category**

Prevention

**3****Description**

Control group: No specific action is taken

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Asghar Farahani

**Street address**

Hokama St, Motahari BLVD  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6514845471  
**Phone**  
+98 81 3264 0022  
**Email**  
besat@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Asghar Farahani  
**Street address**  
Shahid Fahmideh BLVD  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838698  
**Phone**  
+98 81 3251 6632  
**Email**  
Info.Research@umsha.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Khatiban  
**Position**  
Associated Professor  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shahid Fahmideh BLVD  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838698  
**Phone**  
+98 81 3838 0320  
**Email**  
mahnaz.khatiban@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
asghar Farahani  
**Position**  
Master of science Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shahid Fahmideh BLVD  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838698  
**Phone**  
+98 81 3822 4864  
**Email**  
asghar.farahani@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Asghar Farahani  
**Position**  
Master of science student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shahid Fahmideh BLVD  
**City**  
Hamadan  
**Province**  
Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3822 4864

**Email**

asghar.farahani@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**

I have no plans for publishing right now

**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