

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
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
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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

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