

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of acupuncture versus metoclopramide on postoperative nausea and vomiting after laparotomy and cholecystectomy: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of acupuncture versus metoclopramide on postoperative nausea and vomiting after laparotomy and cholecystectomy. **Design:** a double blinded randomized clinical trial. **Setting and conduct:** All eligible patients who are candidate for elective laparotomy or cholecystectomy and will refer to the Beasat Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a); candidate for elective laparotomy or cholecystectomy; (b) age of 12 to 70 years. **Exclusion criteria:** (a) narcotic abuse; (b) alcohol abuse; (c) history of neurological or psychological diseases; (d) presence of scar or infection at site of needling on wrist or elbow; (e) history of gastrointestinal disorder or ear diseases that may lead to nausea or vomiting; (f) prolongation of surgery longer than two hours. **Intervention:** Performing acupuncture through inserting special needle at point of P6 in front of the elbow immediately after anesthesia and removing it before intubation and transferring the patient to the recovery room. **Control:** Prescribing single dose of metoclopramide 10 mg intravenously and single dose of dexamethasone 10 mg intravenously before intubation and transferring the patient to the recovery room. **Primary outcome:** Assessing the number of times nausea and vomiting occur during the period that the patient stays in recovery room through question or clinical observation. **Secondary outcome:** local reaction at site of acupuncture needle during the period that the patient stays in recovery room through clinical examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403039014N29**
Registration date: **2014-03-11, 1392/12/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

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Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupuncture versus metoclopramide on

postoperative nausea and vomiting after laparotomy and cholecystectomy: a double blinded randomized clinical trial

Public title

Effect of acupuncture versus metoclopramide on postoperative nausea and vomiting after laparotomy and cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a); candidate for elective laparotomy or cholecystectomy; (b) age of 12 to 70 years. Exclusion criteria: (a) narcotic abuse; (b) alcohol abuse; (c) history of neurological or psychological diseases; (d) presence of scar or infection at site of needling on wrist or elbow; (e) history of gastrointestinal disorder or ear diseases that may lead to nausea or vomiting; (f) prolongation of surgery longer than two hours.

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control group using tossing coin.
Blinding: Although informed consent will be taken from all volunteers, however all interventions including acupuncture and injection of metoclopramide and dexamethasone will be done during anesthesia. Thus the patients are unconscious and will be unaware of the intervention. In addition, the physician, who conduct the intervention is different from the physician who will examine the patients and the examiner will not be aware of the intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2013-09-10, 1392/06/19

Ethics committee reference number

D/P/16/35/9/1687

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

number of times nausea and vomiting occur

Timepoint

during the period that the patient stays in recovery room

Method of measurement

through question and clinical observation

Secondary outcomes

1

Description

local reaction at site of acupuncture needle

Timepoint

during the period that the patient stays in recovery room

Method of measurement

through clinical examination

Intervention groups

1

Description

Performing acupuncture through inserting special needle at point of P6 in front of the elbow immediately after anesthesia and removing it before intubation and transferring the patient to the recovery room.

Category

Treatment - Drugs

2

Description

Prescribing single dose of metoclopramide 10 mg intravenously and single dose of dexamethasone 10 mg intravenously before intubation and transferring the patient to the recovery room.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospital

Full name of responsible person

Dr Shahpour Shoja

Street address

Beasat Hospital, Shahed Square, Behesh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Beasat Hospital

Full name of responsible person

Dr Shahpour Shoja

Position

Resident of Anesthesiology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty