

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing the P6 point stimulation and lack of stimulation in the treatment of nausea and vomiting in patients after laparoscopic cholecystectomy

Protocol summary

Summary

Objectives: Effects of P6 stimulation on post-operative nausea and vomiting, Design: Randomized double-blind clinical trial Setting and conduct: After induction of anesthesia before the surgery is performed acupuncture. Patients were randomized using a random number table in two groups (each group 65 patients). In Group A at the point p6 under sterile conditions with a disposable needle in Group B for at least 15 minutes and no action was taken. After the surgery the patient's spontaneous breathing and level of consciousness is normal and there by trained personnel using visual criteria, the incidence of nausea and vomiting, patients at hours 1, 2 and 4 is recorded after surgery. Participants including: patients undergo laparoscopic cholecystectomy Inclusion criteria: Age between 18 to 80; ASA class I and II Exclusion criteria: Coagulopathies; ulceration; edema and fracture at the site of stimulation Intervention: P6 point of acupuncture in the treatment group and the control group did not do anything. Main outcome measures (variables): Nausea and vomiting after surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110224799N2**
Registration date: **2016-06-12, 1395/03/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Masoud Saghafinia

Name of organization / entity

Baqiyatallah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3207

Email address

dr_saghafi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2005-07-23, 1384/05/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the P6 point stimulation and lack of stimulation in the treatment of nausea and vomiting in patients after laparoscopic cholecystectomy

Public title

Effects of P6 stimulation on post-operative nausea and vomiting in laparoscopic cholecystectomy patients

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Age between 18 to 80; ASA class I and II exclusion criteria: Coagulopathies; ulceration; edema; fracture at the site of stimulation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of
Medical Sciences

Street address

Postal code: 1435917541, Mollasadra St, Sheikh
Bahae, St, Tehran

City

Tehran

Postal code

1435917541

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

lr.bmsu.rec.1394.155

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

Postoperative nausea

Timepoint

After awake in 1, 2 and 4 hours

Method of measurement

According to VAS scale from 0 to 10

Secondary outcomes

1

Description

Vomiting after surgery

Timepoint

After awake in 1, 2 and 4 hours

Method of measurement

Severity of vomiting (mild, moderate, severe)

Intervention groups

1

Description

Intervention 1: at the point p6 under sterile conditions
with disposable needles for at least 15 minutes and bran
is not important

Category

Prevention

2

Description

Intervention 2: Not applicable

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery department of Baqiyatallah university of
medical sciences

Full name of responsible person

Majid Amini

Street address

Postal code: 1435917541, Mollasadra, St - Sheikh, St,
Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Baqiyatallah University
of Medical Sciences

Full name of responsible person

Majid Amini

Street addressPostal code: 1435917541, Mollasadra St, Sheikh
Bahaee, St, Tehran**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Baqiyatallah 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**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Majid Amini

Position

Student/Anesthesiology resident

Other areas of specialty/work**Street address**Postal code: 1435917541, Mollasadra St, Sheikh
Bahaee, St, Tehran**City**

Tehran

Postal code

1435917541

Phone

+98 21 2680 0103

Fax**Email**

amini_m1350@yahoo.com

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Hassan Araghizadeh

Position

Faculty member/Anesthesiologist

Other areas of specialty/work**Street address**Postal code: 1435917541, Mollasadra St, Sheikh
Bahaee, St, Tehran**City**

Tehran

Postal code

1435917541

Phone

+98 21 2680 0103

Fax**Email**

amini_m1350@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Majid Amini

Position

Student/Anesthesia resident

Other areas of specialty/work**Street address**Postal code: 1435917541, Mollasadra St, Sheikh
Bahaee, St, Tehran**City**

Tehran

Postal code**Phone**

+98 21 2680 0103

Fax**Email****Web page address****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*