Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Masoud Saghafinia
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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 Bahaee, St, Tehran
City
Tehran
Postal code
1435917541
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
Ir.bmsu.rec.1394.155

Health conditions studied

1

Description of health condition studied
postoperative nasuea and vomiting
ICD-10 code
k91.0
ICD-10 code description
Vomiting following gastrointestinal surgery

Primary outcomes

1

Description
Postperative 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, sever)

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 departemant of Baqiyatallah university of medical sciences
Full name of responsible person
Majid Amini
Street address
Postal code: 1435917541, Mollasadra, St - Sheikh, St, Tehran
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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
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Postal code: 1435917541, Mollasadra St, Sheikh Bahaee, St, Tehran
City
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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, 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
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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