

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of low pressure versus high pressure gas injection at abdominal cavity on post operative nausea & vomiting after laparoscopic cholecystectomy.

Protocol summary

Summary

Post operative nausea & vomiting (PONV) is distressing complication of anesthesia and surgery, with a relatively high incidence in women undergoing laparoscopic cholecystectomy. Therefore, this study aimed to investigate occurrence and severity of PONV of low pressure (LP [8mm/Hg]) in comparison to standard pressure (SP [13mm/Hg]) pneumoperitoneum. Fifty consecutive patients qualified for elective laparoscopic cholecystectomy were randomly allocated to either SP group (n=25) & LP group (n=25), after categorized in similar age group, provided that they belonged to class 1-2 of ASA. On the day before surgery, patients were asked to provide a detailed medical history, including any history of PONV or motion sickness, smoking habits, and any other questions. Antiemetic prophylaxis was not received. At first, patients will be anesthetized with the following medications: midazolam 1-2mg, fentanyl 2 mcg/kg, thiopental 3-5 mg/kg & cisatracurium 0.1 mg/kg. At surgical time, patients were monitored & assessed for BP & HR. After surgery, they were assessed for emetic symptoms within the first post-operative 24 h (at five different times). So all of the obtained information have been compared in two groups (LP & SP).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013013112320N1**

Registration date: **2013-11-05, 1392/08/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-05, 1392/08/14

Registrant information

Name

Nader Hamoonpou

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Jundishapour University of Medical Sciences.

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of low pressure versus high pressure gas injection at abdominal cavity on post-operative nausea & vomiting after laparoscopic cholecystectomy.

Public title

Assessment of the effect of intra-abdominal pressure during operation on nausea & vomiting after laparoscopic cholecystectomy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Elective operation; female patients with the ASA 1-2. Exclusive criteria: Pregnancy; antiemetic drugs consumption at 24 hours before surgery; motion sickness disease; history of frequent nausea & vomiting for any reason; history of migraine or vertigo; smokers patients; use of Dexamethason or Gabapentin before surgery for any reason; when excusion of surgery or its condition have been changed"prolonged procedure or changing of surgical plan"for example: laparoscopy converts to laparatomy.

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapour University of Medical Sciences , Vice
Chancellory for Research & Technology Developemen

Street address

Vice Chancellory for Research & Technology
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, Esfand Aven. , Golestan boulevard .

City

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Postal code

6135715794

Approval date

2012-12-22, 1391/10/02

Ethics committee reference number

EPH-675

Health conditions studied

1

Description of health condition studied

Nausea & Vomiting after laparoscopic Cholesystectomy

ICD-10 code

K91.0

ICD-10 code description

Nausea & Vomiting , Following Gastrointestinal Surgery.

Primary outcomes

1

Description

Nausea after Laparoscopic Cholecystectomy

Timepoint

Recovery (time 0) - 4 - 8 - 12 & 24 hours

Method of measurement

Patient symptoms consistent with graded scale of one to five

2

Description

Vomiting after Laparoscopic Cholesystectomy

Timepoint

Recovery (time 0) - 4 - 8 - 12 & 24 hours

Method of measurement

Patient symptoms consistent with graded scale of one to five

Secondary outcomes

empty

Intervention groups

1

Description

At group 1 patients recieve induction with drugs without antiemetic effects then from the surgeon will be asked to do laparoscopic cholecystectomy with the least amount of gas injection into the abdominal cavity ,to conclude that to postoperative nausea & vomiting ,be compared with the other patient at group 2 that had been operated with high gas pressure.

Category

Early detection

2

Description

At group 2 patients recieve induction with drugs without antiemetic effects then from the surgeon will be asked to do laparoscopic cholecystectomy with the maximum of standard pressure of gas injection into the abdominal cavity,to conclude that to postoperative nausea & vomiting,be compared with the other patients at group 1 that had been operated with low gas pressure.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Aria Hospital

Full name of responsible person

Nader Hamoonpou

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapour University of Medical Sciences Vice
Chancellory for Research and Technology
Development

Full name of responsible person

mostafa fegghi

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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

Jundishapour University of Medical Sciences Vice
Chancellory for Research and Technology Development

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**

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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