Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 laparascopic cholesystectomy.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 laparascopic cholecystectomy were randomly allocated to either SP group (n=25) &LP group (n=25) , after categorized in similar age grou,provided that they belonged to class 1-2 of ASA. On the day before surgery,patients were ask to provide a detailed medical history,including any history of PONV or motion sickness,smoking habits any any other questions.antiemetic prophylaxis was not recieved. At first patients will be anesthetized with the followingmedications; midazolam 1-2mg , fentanyle 2 mcg/kg , thiopental 3-5 mg/kg & cisatracurium 0.1 mg/kg. At surgical time,patients were monitired & assessed for BP & HR ,after surgery they were assessed for emetic symptoms within the first post operative 24 h (at five differ times). So all of the obtained information have been compaired in two group (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

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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 Gabapenthin before surgery for any reason; when excuesion 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 Developement , Ahwaz Jundishapour Medical Scienses , Esfand Aven. , Golestan boulevard .

City
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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 laparascopic Cholesystectomy

ICD-10 code
K91.0

ICD-10 code description
Nausea & Vomiting , Following Gastrointestinal Surgery.

Primary outcomes

1

Description
Nausea after Laparascopic 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 Laparascopic 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 laparascopic 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 laparascopic 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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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