Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Postoperative Hepatic Function Between Low Pressure And Standard Pressure Penumoperitnoeum In Laparoscopic Cholecystectomy

Protocol summary

Summary

The purpose of this study was to compare the effect of two insufflation pressures on liver enzymes in patients who underwent laparoscopic cholecystectomy. Patients with acute chlocystitis scheduled for laparoscopic cholecystectomy were enrolled in the study. Exclusion criteria include need for changing from laparoscopic to open approach during surgery, need for increasing abdominal pressure in low pressure pneumoperitoneum group and gallbladder rupture during surgery. 130 patients were included in the study which were randomly assigned to two groups. In group 1 and group 2, 8 mmHg pressure pneumoperitoneum and 14 mmHg pressure pneumoperitoneum were used, respectively. The primary outcome measure was liver enzymes. The level of liver enzymes was measured preoperatively and 24 and 48 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205226925N2**
Registration date: **2015-03-09, 1393/12/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-09, 1393/12/18

Registrant information

Name

Shirzad Nasiri

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-01-01, 1391/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Postoperative Hepatic Function Between Low Pressure And Standard Pressure Penumoperitnoeum In Laparoscopic Cholecystectomy

Public title

Intra-abdominal Pressure During Laparoscopic Cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Indication for laparoscopic cholecystectomy in patients with acute cholecystitis
Exclusion criteria: Need for changing from laparoscopic to open approach during surgery; Need for increasing abdominal pressure in 8 mmhg pneumoperitoneum group to 14 mmhg; Gallbladder rupture during surgery

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Etics Committee

Street address

6 th Floor, Central Building of Tehran University of Medical Sciences, Gods St., Keshavarz Ave.

City

Tehran

Postal code

Approval date

2011-08-16, 1390/05/25

Ethics committee reference number

130/823/90د

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Alanine aminotransferase

Timepoint

Before operation and 1 and 2 days after surgery

Method of measurement

Blood sample analysis

2

Description

Aspartate aminotransferase

Timepoint

Before operation and 1 and 2 days after surgery

Method of measurement

Blood sample analysis

Secondary outcomes

1

Description

Gamma-glutamyl transferase

Timepoint

Before operation, 1 and 2 days after surgery

Method of measurement

Blood sample analysis

2

Description

Alkaline phosphatase

Timepoint

Before operation, 1 and 2 days after surgery

Method of measurement

Blood sample analysis

3

Description

Total Bilirubin

Timepoint

Before operation, 1 and 2 days after surgery

Method of measurement

Blood sample analysis

4

Description

Direct billirubin

Timepoint

Before operation, 1 and 2 days after surgery

Method of measurement

Blood sample analysis

5

Description

Lactate dehydrogenase

Timepoint

Before operation, 1 and 2 days after surgery

Method of measurement

Blood sample analysis

Intervention groups

1

Description
Intervention: Eight mmhg pressure pneumoperitoneum
Control: Fourteen mmhg pressure pneumoperitoneum
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital, General Surgery Ward
Full name of responsible person
Dr. Shirzad Nasiri
Street address
General Surgery Ward, Shariati Hospital, North Kargar st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Fotuhi
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Tehran University of Medical Sciences Building,Gods St., Keshavarz Ave.
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Tehran
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, Tehran 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
Tehran University of Medical Sciences
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Person responsible for updating data

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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