

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of Hemodynamic Signs and Level of Abdominal Pain in Using High and Low Pressures of Carbon Dioxide Gas in Patients Undergo Laparoscopic Cholecystectomy

Protocol summary

Summary

Objectives: The aim of this study is to compare of the effects of using two different pressures of carbon dioxide gas in patients who undergo laparoscopic cholecystectomy. **Design:** In this clinical trial, 60 patients aged 20-70 years who are candidate for laparoscopic cholecystectomy will be randomly divided into two groups. For the first group carbon dioxide pressure will be 7-10 mmhg (low pressure) and for the second group it will be 12-14 mmhg (high pressure). Each group consists of 30 patients. **Setting and conduct:** The general anesthesia protocol and surgical method are the same in both groups. Two surgeons with similar resume will perform the operations using the standard 4-port laparoscopic cholecystectomy. The only difference between the groups is the pressure of CO2 gas. **Major Inclusion and Exclusion criteria:** Patients who are candidate for laparoscopic cholecystectomy without ruptured gallbladder or empyema. **Intervention:** Usage of CO2 gas with low or high pressure during the operation. **Main outcome measures (variables):** Hemodynamic signs, nausea and vomiting and abdominal and shoulder pain will be measured at 1, 3, 6, 12 and 24 hours after the surgery and mean liver tests before and after the operation will be assessed in patients of the two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014121420309N1**

Registration date: **2015-01-26, 1393/11/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-26, 1393/11/06

Registrant information

Name

Fereshteh Esmaili

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

f.esmaeili@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Hemodynamic Signs and Level of Abdominal Pain in Using High and Low Pressures of Carbon Dioxide Gas in Patients Undergo Laparoscopic Cholecystectomy

Public title

Evaluating Intra-abdominal Gas related Symptoms

During Cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 20-70 years who are candidate for laparoscopic cholecystectomy
Exclusion criteria: Rupture of the gallbladder, empyema, common bile duct stones, history of major upper abdominal surgeries, pregnancy, patients with a BMI (Body Mass Index) greater than 30 or less than 19, fatty liver grade 3 or 4, abnormalities of liver enzymes before surgery

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In the present study patients will be randomly divided into two groups with the usage of randomized block design. During the surgery and after that, the patients and the surgeons won't be aware of the used carbon dioxide pressure for the laparoscopy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Boulevard

City

Qazvin

Postal code

Approval date

2014-03-03, 1392/12/12

Ethics committee reference number

28.20.8501

Health conditions studied

1

Description of health condition studied

Cholecystectomy (Laparoscopic)

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other parts of digestive tract

2

Description of health condition studied

Disorders related to gallbladder and bile ducts

ICD-10 code

K87.0

ICD-10 code description

Disorders of gallbladder and biliary tract in diseases classified elsewhere

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

At admission, during the operation, 1, 3 and 6 hours after the surgery

Method of measurement

Monitoring

2

Description

Heart rate

Timepoint

At admission, during the operation, 1, 3 and 6 hours after the surgery

Method of measurement

Monitoring

3

Description

Body Temperature

Timepoint

At admission, during the operation, 1, 3 and 6 hours after the surgery

Method of measurement

Thermometer

Secondary outcomes

1

Description

Nausea & vomiting after Laparoscopic Cholecystectomy

Timepoint

1, 3, 6, 12 and 24 hours after the operation

Method of measurement

Verbal Rating Scale Questionnaire

2

Description

Abdominal and shoulder pain after Laparoscopic Cholecystectomy

Timepoint

1, 3, 6, 12 and 24 hours after the operation

Method of measurement

Verbal Rating Scale Questionnaire

3

Description

Liver Tests

Timepoint

Before and after the operation

Method of measurement

Laboratory Data

Intervention groups

1

Description

First intervention group (low pressure): Usage of carbon dioxide gas with percent purity of 99% from Qazvin Oxygen Company, gas pressure: 7-10 mmhg

Category

Prevention

2

Description

Second intervention group (high pressure): Usage of carbon dioxide gas with percent purity of 99% from Qazvin Oxygen Company, gas pressure: 12-14 mmhg

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat General Hospital

Full name of responsible person

Doctor Fereshteh Esmaili

Street address

Taavon Square

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Qazvin University of

Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Boulevard

City

Qazvin

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, Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Doctor Fereshteh Esmaili

Position

Resident of General Surgery

Other areas of specialty/work

Street address

General Velayat Hospital, Taavon Square

City

Qazvin

Postal code

Phone

+98 28 3379 0620

Fax

Email

dr.esmaili83@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Doctor Alireza Mohammadzadeh

Position

Assistant Professor

Other areas of specialty/work

Street address

General Velayat Hospital, Taavon Square

City

Qazvin

Postal code**Phone**

+98 28 3379 0620

Fax**Email**

dr.esmaili83@gmail.com

Web page address**Postal code****Phone**

+98 28 3379 0620

Fax**Email**

dr.esmaili83@gmail.com

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

Qazvin University of Medical Sciences

Full name of responsible person

Doctor Fereshteh Esmaili

Position

Resident of General Surgery

Other areas of specialty/work**Street address**

Velayat Hospital, Taavon Square

City

Qazvin

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*