

# 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*