# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of the effect of standard gas pressure with low intra-abdominal co2 pressure on postoperative shoulder pain in laparoscopic cholecystectomy patients

## Protocol summary

**Study aim**
Determining the effect of standard pressure with low intra-abdominal co2 pressure on postoperative shoulder pain in laparoscopic cholecystectomy patients.

**Design**
A triple blind clinical trial with a control group, with parallel groups, phase 3 of 34 patients.Allocation of samples to intervention and control groups is done non-randomly

**Settings and conduct**
This study is conducted in patients with symptomatic gallstones who refer to Qazvin Velayat hospital and are candidates for laparoscopic cholecystectomy according to the order of the patient's surgeon. the patient enters one of 2 groups A (standard intra-abdominal co2 pressure), group B (low intra-abdominal co2 pressure). Participant and outcome assessor and data safety and monitoring committee are blinded

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients aged 25 to 70 who have symptomatic gallstones or chronic cholecystitis. Exclusion criteria: pregnant women Age < 25 years and > 70 years Gallbladder carcinoma and its abnormalities Previous upper abdominal surgery Patients who do not want to participate in the study Patients with a history of drug or alcohol abuse

**Intervention groups**
Group A (standard intra-abdominal co2 pressure), group B (low intra-abdominal co2 pressure)

**Main outcome variables**
postoperative shoulder pain

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20231120060124N1**
Registration date: **2023-12-19, 1402/09/28**
Registration timing: **prospective**

Last update: **2023-12-19, 1402/09/28**
Update count: **0**

**Registration date**
2023-12-19, 1402/09/28

**Registrant information**

**Name**
Alireza Abadi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-12-22, 1402/10/01

**Expected recruitment end date**
2024-04-20, 1403/02/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the effect of standard gas pressure with low intra-abdominal co2 pressure on postoperative shoulder pain in laparoscopic cholecystectomy patients

**Public title**
Investigating the effect of intra-abdominal CO2 gas pressure on shoulder pain after laparoscopic cholecystectomy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients aged 25 to 70 who are diagnosed with symptomatic gallstones or chronic cholecystitis
**Exclusion criteria:**
Pregnant women aged <25 years and >70 years emergency cholecystectomy jaundice intraoperative injury to the intestine or bile duct intraoperative bleeding gangrenous cholecystitis or emphysema obstructive jaundice choledocholithiasis coagulopathy rupture of the gallbladder during Surgery or damage to the common bile duct cholangitis pancreatitis gallbladder carcinoma and its abnormalities previous upper abdominal surgery patients who do not want to participate in the study acute cholecystitis problems Nerves and psyche failure of the surgeon to use CO2 pressure
**Age**
From **25 years** old to **70 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **34**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
This is a triple-blind type of experiment, which will be blind for the people participating in the study and evaluating the outcome and Data Safety and Monitoring Committee. In the consent form to participate in the study, it is written for the patient that his presence does not necessarily mean intervention but may be included in the control group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of qazvin University of Medical Sciences
**Street address**
Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3413996134
**Approval date**
2023-10-15, 1402/07/23
**Ethics committee reference number**
IR.QUMS.REC.1402.189

## Health conditions studied

**1**

**Description of health condition studied**
Shoulder pain after laparoscopy
**ICD-10 code**
M25.5
**ICD-10 code description**
Pain in joint

## Primary outcomes

**1**

**Description**
Shoulder pain
**Timepoint**
3, 6, 12 and 24 hours after the operation
**Method of measurement**
visual analog score (VAS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: a 10 mm port is inserted through the incision below the umbilicus using the Hasson method, and the abdominal cavity is filled with CO2 gas in group B with a low intra-abdominal pressure of 7-7 mm Hg, and the camera is also inserted into the abdomen through the same port. Under the camera guide, another 10 mm port will be placed under the xiphoid process and two 5 mm ports in the subcostal area. During the process of creating pneumoperitoneum, intra-abdominal pressure, gas volume and gas flow rate are checked, and gallbladder removal will be performed in group B with a

low intra-abdominal pressure of 7-8 mmHg. The air behind the liver is completely sucked.

**Category**

Treatment - Surgery

**2**

**Description**

A 10 mm port is inserted through the incision below the umbilicus using the Hasson method, and the abdominal cavity is filled with CO2 gas in group A with a standard intra-abdominal pressure of 14-15 mm Hg, and the camera is also inserted into the abdomen through the same port under the camera guide. Another 10 mm port will be placed under the xiphoid appendage and two 5 mm ports will be placed in the subcostal region. During the process of creating pneumoperitoneum, intra-abdominal pressure, gas volume and gas flow rate are checked, and gallbladder removal will be performed in group A with a standard intra-abdominal pressure of 14-15 mmHg. The air behind the liver is completely sucked.

**Category**

Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Velayat hospital

**Full name of responsible person**

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## Sponsors / Funding sources

**1**

**Sponsor**

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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**

Qazvin University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Alireza Abadi

**Position**

Resident

**Latest degree**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available