

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

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

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

Medical doctor

Other areas of specialty/work

General Surgery

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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