

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the relationship between co2 insufflation rate during laparoscopic surgery and the shoulder pain after it, in patients undergoing laparoscopic cholecystectomy

Protocol summary

Summary

Objective: Evaluation of relation between co2 blowing speed during laparoscopy surgery and shoulder pain after surgery in patients with laparoscopic cholecystectomy in Kowsar hospital Study design: systematic random (toss); without placebo control; single central. The study population: patients with gallstone that will be undergoing laparoscopic cholecystectomy surgery. Inclusion criteria: all patients with gallstone that will be undergoing laparoscopic cholecystectomy surgery. Exclusion criteria: drug addiction; patients who receive sedation exception with shoulder pain; patients who need drains after surgery; patients who associated with bile leakage or bleeding during surgery; patients who have laparoscopic surgery become to open surgery. Sample size, intervention, intervention time, outcome of study: 100 patients with gallstones referred to operating room in Kowsar hospital that are candidate for laparoscopic cholecystectomy surgery and will be undergoing to surgery. Intervention group: in this group of 50 peoples, patients will be undergoing laparoscopic cholecystectomy surgery and then co2 gas injection will perform from start of laparoscopic surgery with high-speed (7.5 liters per minute) for them. Control group: in this group of 50 patients are undergoing laparoscopic cholecystectomy surgery and co2 gas injection will perform from start of laparoscopic surgery with low-speed (2.5 liters per minute) for them. The number of sedation request in 24 hours after surgery and also shoulder pain in 1, 6, 12 and 24 hours after surgery was checked with verbal rating scale method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060125732N17**

Registration date: **2017-06-18, 1396/03/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-18, 1396/03/28

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-01-03, 1395/10/14

Expected recruitment end date

2018-01-04, 1396/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the relationship between co2 insufflation rate during laparoscopic surgery and the shoulder pain

after it, in patients undergoing laparoscopic cholecystectomy

IR.SEMUMS.REC.1395.158

Public title

Evaluation of the relationship between co2 insufflation rate during laparoscopic surgery and the shoulder pain after it, in patients undergoing laparoscopic cholecystectomy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: all patients with gallstone that will be undergoing laparoscopic cholecystectomy surgery.

Exclusion criteria: drug addiction; patients who receive sedation exception with shoulder pain; patients who need drains after surgery; patients who associated with bile leakage or bleeding during surgery; patients who have laparoscopic surgery become to open surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Postal code

3514799442

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Shoulder pain

ICD-10 code

M25.5

ICD-10 code description

Pain in joint

Primary outcomes

1

Description

Shoulder pain intensity

Timepoint

1, 6, 12 and 24 hours after surgery.

Method of measurement

verbal rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group of 50 peoples, patients will be undergoing laparoscopic cholecystectomy surgery and then co2 gas injection will perform from start of laparoscopic surgery with high-speed (7.5 liters per minute) for them.

Category

Diagnosis

2

Description

Control group: in this group of 50 peoples, patients are undergoing laparoscopic cholecystectomy surgery and co2 gas injection will perform from start of laparoscopic surgery with low-speed (2.5 liters per minute) for them.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Setareh Soltany

Street address

Kosar Hospital, Street Amin, Semnan

City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences, Deputy of
Research and Technology

Full name of responsible person
Mohammadreza Asgari

Street address
Semnan University of Medical Sciences, Deputy of
Research and Technology, Basij Blvd, Semnan

City
Semnan

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**
Yes

Title of funding source
Semnan University of Medical Sciences, Deputy of
Research and Technology

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
Semnan University of Medical Sciences

Full name of responsible person
Setareh Soltany

Position
General surgery

Other areas of specialty/work

Street address
Semnan University of Medical Sciences, Blvd Basij,
Semnan

City
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

Email
are20935@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Setareh Soltany

Position
General surgery

Other areas of specialty/work

Street address
Semnan University of Medical Sciences, Blvd Basij,
Semnan

City
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

Email
are20935@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Setareh Soltany

Position
General surgery

Other areas of specialty/work

Street address
Semnan University of Medical Sciences, Blvd Basij,
Semnan

City
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

Email
are20935@gmail.com

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