Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Study of the effect of decrease in carbon dioxide pressure on pain in patients with cholecystitis after laparoscopic cholecystectomy

Protocol summary

Study aim
Study of the effect of decrease in carbon dioxide pressure on pain in patients with cholecystitis after laparoscopic cholecystectomy

Design
Clinical trial with control group, with parallel groups, double blind, randomized, phase 3 on 72 patients, Random allocation software was used to randomize.

Settings and conduct
Patients with a diagnosis of cholecystitis who are admitted to Ayatollah Mousavi Hospital in Zanjan are studied. In the surgical procedure, standard pressure gas(12-14mmHg) is used in one group and low pressure(8-10mmHg) in the other group. Patients will be cared for and followed up at 6-12-24 hours after surgery. Follow-up of patients by examining the amount of pain in the Visual Analog Scale(VAS) and the need for analgesics.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cholecystitis and Patient satisfaction
Exclusion criteria: Kidney disease, Liver disease, Heart disease, CNS disease, Pregnant women, Addiction, Patient dissatisfaction, History of abdominal surgery

Intervention groups
The intervention group includes patients with cholecystitis who undergo surgery with low pressure carbon dioxide(8-10mmHg) and control group includes patients with cholecystits who undergo surgery with standard pressure carbon dioxide(12-14mmHg).

Main outcome variables
Patients' pain after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210830052338N1**
Registration date: **2021-10-23, 1400/08/01**
Registration timing: **retrospective**

Last update: **2021-10-23, 1400/08/01**
Update count: **0**

Registration date
2021-10-23, 1400/08/01

Registrant information

Name
Naser Keikhali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3666 4489

Email address
nkeikhali@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of decrease in carbon dioxide pressure on pain in patients with cholecystitis after laparoscopic cholecystectomy

Public title
Ṡtudy of the effect of decrease in carbon dioxide pressure on pain in patients with gallbladder

inflammation after laparoscopy

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Cholecystitis Patient satisfaction

Exclusion criteria:

Liver disease Heart disease CNS disease Kidney disease Pregnant women Addiction History of abdominal surgery Patient dissatisfaction Use of analgesics

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study at least 30 samples were calculated in each intervention and control group (Based on the sample size formula with a type one error 5% and 80% power) which is required according to the type of randomization to 36 samples in each group. Patient randomization is done on Block Randomization basis with permutations ABAB, ABBA, AABB, BBAA, BABA, BABA. Each block is randomly selected and patients will be assigned to two groups A and B based on the permutation sequence. In Block Randomization the number of participants, 3 patients in each block, in the consecutive time intervals are entered into intervention and control groups. This study has parallel design namely any group of participants exposed to one of the study interventions. For random assignment of Random allocation software is used. These random sequencing production software in addition to simple randomization are able to generate random sequencing by blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind for participant, clinical care, researcher, impact assessor and data analyzer so that these people are not informed of carbon dioxide gas pressure and the only surgeon is notified of gas pressure.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of medical Sciences

Street address

Zanjan University of Medical Sciences , Shahid Avini dormitory

City

Zanjan

Province

Zanjan

Postal code

4513956111

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.ZUMS.REC.1400.211

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K81

ICD-10 code description

Cholecystitis

Primary outcomes

1

Description

Severity of pain

Timepoint

6 ,12 ,24 hours after the operation

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are candidate for laparoscopic cholecystectomy surgery with low carbon dioxide gas pressure(8-10mmHg)

Category

Treatment - Surgery

2

Description
Control group: Patients are candidate for laparoscopic cholecystectomy surgery with standard carbon dioxide gas pressure(12-14mmHg)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Yalda Yusefi
Street address
Zanjan , Ayatollah Mousavi Hospital
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3345 6006
Email
Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
Street address
Zanjan University of Medical science
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4515613191
Phone
+98 24 3315 6141
Email
research@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Naser Keikhali
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Assistant Professor

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Other areas of specialty/work
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after identifying individuals.

When the data will become available and for how long
Access period starts from 2022

To whom data/document is available
The data will be available to all researchers working in academic and scientific institutions, as well as to those working in industry.

Under which criteria data/document could be used
The data will be available to start a similar clinical trail.

From where data/document is obtainable
Individuals cab refer to dr.yalda.yusefi@gmail.com to receive data.

What processes are involved for a request to access data/document
The data will be provided to the applicant at the earliest opportunity.

Comments