Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of standard pressure versus low pressure pneumoperitoneum with surgery site suction on the severity of shoulder pain in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Determining the effect of comparing standard pressure with low pressure pneumoperitoneum with surgery site suction on the severity of shoulder pain in patients undergoing laparoscopic cholecystectomy

Design
A clinical trial with a control group, with a parallel group, one-sided blind and patients unaware of the group assigned to them, randomized, coin toss was used on 70 patients who were candidates for laparoscopic cholecystectomy.

Settings and conduct
The research site will be the operating room and surgery wards of Motahhari and Peymaniyeh hospitals in Jahrom. The researcher selects patients according to the list of patients ready for cholecystectomy surgery and after explaining the reason for the research and obtaining consent and if there are criteria. Admission completes a questionnaire for patients. The researcher assures patients that their name will be kept confidential, they will be free to leave the study at any time if they wish to leave the study. Patients are measured at specific times by attending their bedside.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 70 years who are candidates for laparoscopic cholecystectomy surgery - having ASA1,2 - elective laparoscopic cholecystectomy - informed consent to participate in the study

Intervention groups
Intervention group 1: Standard pressure group of pneumoperitoneum with carbon dioxide pressure of 12 to 15 mm Hg Intervention group 2: Low pressure group of pneumoperitoneum with carbon dioxide pressure of 8 to 11 mm Hg with suction area

Main outcome variables
Severe postoperative shoulder and abdominal pain, preoperative anxiety, rate of postoperative analgesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210502051161N1**
Registration date: **2021-05-23, 1400/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-23, 1400/03/02**
Update count: **0**

Registration date
2021-05-23, 1400/03/02

Registrant information

Name
Hamidreza Nejati
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 5372 3872
Email address
hamidrezaa891425@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of standard pressure versus low pressure pneumoperitoneum with surgery site suction on the severity of shoulder pain in patients undergoing laparoscopic cholecystectomy

Public title
The effect of standard pressure and low pressure of pneumoperitoneum with surgery site suction on pain intensity in laparoscopic cholecystectomy patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having gallstones without serious complications Elective laparoscopic cholecystectomy Age between 18 and 70 years Having ASA1,2 Having informed consent to participate in the study

Exclusion criteria:
Having a history of major abdominal surgery Having ASA3 Pregnancy and breastfeeding Drug addiction and the use of strong anti-anxiety drugs Coagulation problems Conscious dissatisfaction to participate in the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple randomization method is used. Using coin tossing, the intervention group is determined, so that if the side is lined, patients are in the intervention group, and if the side is not lined, patients are in the group. Will be controlled. The unit is individual randomization. The method of hiding random allocation in this study is the SNOSE method. In this method, first a random sequence is performed, then based on the sample size of the research, a number of envelopes with aluminum wrappers are prepared and each of the random sequences created is registered on a card and the cards are placed inside the envelope. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface of the envelopes. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants to study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed. In the implementation phase of the random allocation process of this study, cases such as the individual who created the random sequence, the person who examined the participants in terms of inclusion and exit criteria, and the participants who studied and participated in the study. It is intended that three separate individuals perform the randomization process without being aware of the actions of other researchers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are told about standard pneumoprotein pressure and low pneumoperitoneum pressure, but are not aware of which group they belong to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamedan University of Medical Sciences

Street address
Shahid Fahmideh, in front of People's Park

City
hamedan

Province
Hamadan

Postal code
6517838678

Approval date
2021-05-02, 1400/02/12

Ethics committee reference number
IR.UMSHA.REC.1400.131

Health conditions studied

1

Description of health condition studied
Laparoscopic cholecystectomy

ICD-10 code
K80.0

ICD-10 code description
Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description
Severe shoulder and abdominal pain after surgery

Timepoint
Two, six, twelve and twenty-four hours after the operation

Method of measurement

10 point pain ruler

2

Description
Rate of request for postoperative analgesic
Timepoint
Six, twelve and twenty-four o'clock after the operation
Method of measurement
The amount and dose of medication used for the patient

Secondary outcomes

empty

Intervention groups

1

Description
Use of carbon dioxide gas with 99% purity made by Qazvin Oxygen Company, gas pressure: 8 to 11 mm Hg, use of operation area suction
Category
Prevention

2

Description
Control group: Use of carbon dioxide gas with 99% purity made by Qazvin Oxygen Company, gas pressure: 12-14 mm Hg
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
General Motahhari and General Peymaniyeh Hospital
Full name of responsible person
Hamidreza Nejati
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
hamidrezaa891425@gmail.com

2

Recruitment center
Name of recruitment center
General Motahhari and General Peymaniyeh Hospital
Full name of responsible person
Hamidreza Nejati
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
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Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
hamidreza891425@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Doctor Behzad Imani
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
behzadiman@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Hamidreza Nejati
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
operating room
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
hamidrezaa891425@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Doctor Behzad Imani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
behzadiman@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Hamidreza Nejati
Position
Master student operating room
Latest degree
Bachelor
Other areas of specialty/work
operating room
Street address
Shahid Fahmideh St., in front of People Park, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3525 0182
Email
hamidrezaa891425@gmail.com

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