

# 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

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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

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Doctor Behzad Imani

##### Street address

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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

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**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

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Hamidreza Nejati

**Position**

Master student operating room

**Latest degree**

Bachelor

**Other areas of specialty/work**

operating room

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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