

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### A comparative study on the postoperative effect of Supine and Trendelenburg positions in reducing shoulder pain in patients undergoing laparoscopic cholecystectomy surgery

#### Protocol summary

##### Study aim

Investigating the effect of using supine and Trendelenburg positions after surgery in reducing shoulder pain in patients undergoing laparoscopic cholecystectomy.

##### Design

Clinical trial with case and control group, with parallel groups, no blinding possible, randomization method in the form of random blocks of four, total sample size 58 people

##### Settings and conduct

During the surgery, the researcher goes to the operating room of Ba'ath Hospital in Hamedan and after obtaining informed consent, the patients will be randomly assigned to one of the case and control groups. In full recovery, they will be placed in the 20-degree Trendelenburg position for half an hour, but in the control group, patients will be placed in the supine position in recovery after the operation is completed and fully awake. The method of data collection in this study includes recording the basic information of patients, including age, gender, weight, and history of surgery (which is supplemented by medical records and interviews) and using the NRS scale to measure the amount of shoulder pain. The NRS scale with Questioning of the patient and in case of discharge, it will be completed using a phone call 2, 6, 12, 24, 48, 72 hours after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 years; ASA (I, II) patients; having informed consent. Exclusion criteria include: having a history of high blood pressure; converting surgery to an open method; having a history of gastroesophageal reflux.

##### Intervention groups

research will have a case and control group. In the case group, patients after surgery and wakefulness in recovery will be placed in the Trendelenber position of 20 degrees

for 30 minutes. Also, in the control group, patients after surgery and wakefulness in recovery will be under They will be placed in the supine position

##### Main outcome variables

position; Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230215057419N1**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

##### Registration date

2023-03-01, 1401/12/10

##### Registrant information

##### Name

Alireza Jafarkhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3131 0000

##### Email address

alirezajafarkhani1377@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-04, 1402/01/15

##### Expected recruitment end date

2023-06-21, 1402/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study on the postoperative effect of Supine and Trendelenburg positions in reducing shoulder pain in patients undergoing laparoscopic cholecystectomy surgery

**Public title**

Comparison of the effect of Supine and Trendelenburg positions after surgery in reducing shoulder pain in patients undergoing laparoscopic cholecystectomy.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

age 18-65 years, patients who are classified in class one and two according to the American Association of Anesthesiologists (ASA) based on their physical condition (independent of the surgical method) and finally informed consent to participate in the study. patients who are classified in class one and two according to the American Association of Anesthesiologists (ASA) based on their physical condition (independent of the surgical method) informed consent

**Exclusion criteria:**

Having a history of high blood pressure conversion of surgery to an open method having a history of gastroesophageal reflux Lack of informed consent

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random blocks of four: in this way, four sheets of paper are prepared for randomizing patients. It is written on two sheets of Case and on the other two sheets of Control. The sheets are mixed together and removed by the researcher consecutively without placing them. This operation is repeated for the number of eligible patients and the case or control group of each patient is noted.

**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 of Hamadan University of Medical Sciences

**Street address**

5th floor, Headquarters of the University of Medical Sciences, Shahid Fahmideh St., Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Approval date**

2023-02-20, 1401/12/01

**Ethics committee reference number**

IR.UMSHA.REC.1401.1004

**Health conditions studied****1****Description of health condition studied**

Laparoscopic cholecystectomy

**ICD-10 code**

K80

**ICD-10 code description**

Cholelithiasis

**Primary outcomes****1****Description**

shoulder pain

**Timepoint**

2, 6, 12, 24, 48, 72 hours after the intervention

**Method of measurement**

NRS scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Allocating the Trendelenburg position to the patients after the surgery so that after the surgery is completed and the patient is completely awake, the patient will be placed under the Trendelenburg position of 20 degrees for 30 minutes using recovery beds.

**Category**

Treatment - Surgery

**2****Description**

Control group: allocating supine position to patients after surgery so that after the surgery is completed and the patient is fully awake, she/ He will be placed in supine position for 30 minutes using recovery beds.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Be'sat Hospital in Hamadan

**Full name of responsible person**

Alireza Jafarkhani

**Street address**

Hamedan, Shahid Beheshti Blvd. - Baath Specialist and Subspecialty Hospital

**City**

Hamadan

**Province**

Hamadan

**Postal code**

4541165148

**Phone**

+98 81 3264 0020

**Fax****Email**

Besat@ umsha.ac.ir

**Web page address**<http://besat.umsha.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokohi

**Street address**

5th floor, headquarters of the University of Medical Sciences, Shahid Fahmideh St., Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3131 0000

**Email**

Webda@umsha.ac.ir

**Web page address**<https://www.umsha.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Hamadan 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**

Alireza Jafarkhani

**Position**

MSc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Others

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**City**

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**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3131 0000

**Email**

Webda@umsha.ac.ir

**Web page address**<https://www.umsha.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Postal code**

6517838736

**Phone**

0988131310000

**Email**

Webda@umsha.ac.ir

**Web page address**

<https://www.umsha.ac.ir/>

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Alireza Jafarkhani

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**Latest degree**

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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)**

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