Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 Trendelenberg 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 anl 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 Trendelenberg 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 Trendelenberg 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
Street address
5th floor, Headquarters of the University of Medical Sciences, Shahid Fahmideh St., Hamadan
City
Hamadan
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
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Jafarkhani
Position
MSc Student
Latest degree
Bachelor
Other areas of specialty/work

Others

Street address

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

City

Hamadan

Province

Hamadan

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

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Others

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

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