

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of using an abdominal drain on shoulder pain after gallbladder laparoscopy (PLSP) in patients referred to Velayat Hospital.

Protocol summary

Study aim

Determining the effect of using an abdominal drain on shoulder pain after gallbladder laparoscopy (PLSP)

Design

A clinical trial with a control group, with parallel groups, randomized, number of 34 samples, the allocation of samples to the intervention groups is done according to the surgeon's order and his diagnosis.

Settings and conduct

This study is a double-blind clinical trial that is conducted in patients with symptomatic gallstones who refer to educational and medical centers in the province and are candidates for laparoscopic cholecystectomy according to the order of the surgeon. Hemovac suction drain will be randomly placed under the liver in a group of patients (group A) and the drain will be removed 24 to 48 hours after surgery in the absence of bile. No drain or tube will be placed in group B patients, and both groups will be given the same antibiotics after the operation. Post-operative pain with pethidine 25 mg intravenously once in the post-anesthesia care unit and acetaminophen suppository every 8 hours in the ward will be given as pain relief for patients. Pain assessment 3, 6, 12 and 24 hours after the operation through visual Analog Score (VAS) will be performed. Safety and data monitoring committee and outcome assessor are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 25 to 70 who have symptomatic gallstones or chronic cholecystitis.

Exclusion: Emergency cholecystectomy Jaundice Bad history of alcohol and drug use Explore the common bile duct Subtotal cholecystectomy Gallbladder carcinoma and its abnormalities Previous upper abdominal surgery

Intervention groups

Group A (with abdominal drain), Group B (without drain)

Main outcome variables

Shoulder Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230607058404N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Mohammadamin Karimlu

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0628

Email address

karimlu.amin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using an abdominal drain on shoulder pain after gallbladder laparoscopy (PLSP) in patients referred to Velayat Hospital.

Public title

Investigating the effect of using an abdominal drain on shoulder pain after gallbladder laparoscopy (PLSP)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with symptomatic gallstones or chronic cholecystitis.

Exclusion criteria:

Pregnant women Age less than 25 years and more than 70 years Emergency cholecystectomy Intraoperative injury to the intestine or bile duct Jaundice Bad history of alcohol and drug use Bleeding during surgery Gangrenous cholecystitis or emphysema Cholelithiasis Coagulopathy Rupture of the gallbladder during surgery Explore the common bile duct Subtotal cholecystectomy Cholangitis Pancreatitis Gallbladder carcinoma and its abnormalities Previous upper abdominal surgery

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The information of the checklist is provided by the secretary of the department in which people with national codes are registered to the person in charge of the analysis and statistical analysis of the plan. After entering SPSS and coding 1 and 2, the results of the evaluation will be analyzed by the statistics professor, separating the intervention and control groups (which only the secretary of the department knows about). Whether he did or not is unknown. The analyst and the data safety monitoring committee are not aware of which solution the patients received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of qazvin University of Medical Sciences

Street address

Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin

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Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2023-08-19, 1402/05/28

Ethics committee reference number

IR.QUMS.REC.1402.129

Health conditions studied

1

Description of health condition studied

Post laparoscopic shoulder pain

ICD-10 code

M25.5

ICD-10 code description

Pain in joint

Primary outcomes

1

Description

Shoulder Pain

Timepoint

3, 6, 12 and 24 hours after the operation

Method of measurement

Visual Analog Score (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the surgery, a Hemovac suction drain will be randomly placed under the liver in a series of patients (group A) and the drain will be removed 24-48 hours after surgery in the absence of bile.

Category

Treatment - Surgery

2

Description

Control group: No drain or tube will be placed in group B patients

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Mohammadamin Karimlu

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22 Bahman Blvd., Minoodar region

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mohammadamin Karimlu

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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