

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The evaluation of intraperitoneal irrigation with bupivacaine %0/5 on postoperative pain control of laparoscopic cholecystectomy patients in comparison with the control group

Protocol summary

Study aim

Determining the effect of intraperitoneal irrigation with bupivacaine %0/5 on postoperative pain control of laparoscopic cholecystectomy patients in comparison with the control group

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 92 patients. For randomization, kitset.ir website was used to generate random numbers.

Settings and conduct

At the end of the operation and after laparoscopic cholecystectomy, the bed of the gallbladder and the right hemi-diaphragm and on the liver, in the first group of patients with 100 cc of 0.9% normal saline solution containing 20 ml of 0.5 marcaine and in the second group with 100 cc of normal solution 0.9% saline will be washed for 10 minutes and then all the liquid in the place is suctioned as much as possible, at the end of the operation in both groups of pneumoperitoneum, it will be drained from the entrance of the ports and the air in the back of the liver will also be under active suction.

Participants/Inclusion and exclusion criteria

1. Absence of acute cholecystitis 2. No drug addiction 3. Absence of drug sensitivities 4. Absence of mental disorders 5. Not having diabetes

Intervention groups

The first group of patients were washed with 100 cc of 0.9% normal saline solution containing 20 ml of 0.5 marcaine and in the second group with 100 cc of 0.9% normal saline solution for 10 minutes.

Main outcome variables

Postoperative pain in laparoscopic cholecystectomy patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221212056794N1**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Vahid Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0163

Email address

sums78vhds@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of intraperitoneal irrigation with bupivacaine %0/5 on postoperative pain control of laparoscopic cholecystectomy patients in comparison with the control group

Public title

The evaluation of intraperitoneal irrigation with bupivacaine %0/5 on postoperative pain control of laparoscopic cholecystectomy patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of acute cerebocystitis
Absence of addiction and drug use
Absence of drug sensitivities
Absence of mental disorders
Not having diabetes

Exclusion criteria:

The presence of severe inflammation and adhesion in the operation site, so that it turns the laparoscopic surgery into a surgical procedure
Rupture of the gallbladder and leakage of bile at the operation site
High bleeding during the operation so that there is a possibility of peritoneal irritation due to the blood in the peritoneum
The patient's unwillingness to continue studying after surgery

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

randomization method using the kitset.ir site to generate random numbers will enter one of the 2 studied groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the method of blinding will be double-blind and the participants will be unaware of the intervention group and the researcher who evaluates the pain intensity will be unaware of the outcome of the variables.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Deputy of research and technology of Yasuj university of medical sciences, Shahid Motahari Blvd;
Kohgiluyeh and Boyer-Ahmad Province; Iran.

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-05-18, 1401/02/28

Ethics committee reference number

IR.YUMS.REC.1401.074

Health conditions studied

1

Description of health condition studied

cholecystectomy

ICD-10 code

K91

ICD-10 code description

Intraoperative and postprocedural complications and disorders of digestive system, not elsewhere classified

Primary outcomes

1

Description

Postoperative pain in laparoscopic cholecystectomy patients

Timepoint

After entering the ward and 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with 100 cc of 0.9% normal saline solution containing 20 ml of 0.5 marcaine

Category

Treatment - Surgery

2

Description

Control group: Washed with 100 cc of 0.9% normal saline solution for 10 minutes

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Vahid Salehi

Street address

Shahid Beheshti Hospital, Shahid Mohammad Montazeri St. Yasuj city ; Kohgiluyeh and Boyer-Ahmad Province; Iran.

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2

Recruitment center

Name of recruitment center

Shahid Jalil Hospital

Full name of responsible person

Vahid Salehi

Street address

Shahid Jalil Hospital, Varzesh St; Yasuj city ; Kohgiluyeh and Boyer-Ahmad Province; Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hoseini

Street address

Deputy of research and technology of Yasuj university of medical sciences, Shahid Motahari Blvd; Kohgiluyeh and Boyer-Ahmad Province; Iran.

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Vahid Salehi

Position

Assistant Professor of Surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Shahid Beheshti Hospital, Shahid Mohammad Montazeri St. Yasuj city ; Kohgiluyeh and Boyer-Ahmad Province; Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Vahid Salehi

Position

Assistant Professor of Surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hosein Mohammadzadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

SPSS file

When the data will become available and for how long

A week

To whom data/document is available

researchers

Under which criteria data/document could be used

Improve treatment

From where data/document is obtainable

Dr. Vahid Salehi

What processes are involved for a request to access data/document

A week

Comments