

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Pain preventive effects of different surgical techniques (low-pressure laparoscopy, intra operative ketorolac, and local bupivacaine administration) in female undergoing laparoscopic cholecystectomy.

Protocol summary

Study aim

The main is evaluation the pain-preventive effects of different surgical methods in post op pain of LC .also , their effect will be evaluated inpatients' hospital stay duration ,analgesic consumption after surgery and patients' performance of daily,

Design

This study is a four-arm parallel, standard-controlled, and double-blinded randomized clinical trial. blinded outcome assure and patients .

Settings and conduct

This is a study in minimally invasive surgery field. it will be done in Namazi and Hafez Shiraz' hospital.patients allocated into four group ,after receive defined intervention , we start to gathering data. it' s notable that panties ,data collector ans data assure will be blinded to allocation .

Participants/Inclusion and exclusion criteria

Eligible participants will be females, candidates of elective LC. are healthy otherwise, have ASA score I OR II, and Body Mass Index ۱۸.۵-۳۰ , patients that have a pain catastrophizing scale >۳۰ or unable to speak Persian or currently taking opioids, and had previous hepatobiliary surgery are not eligible for the study .

Intervention groups

Controlled group :taking standard protocols of LC ,without any excess intervention. group II: low intra abdominal CO2 pressure (12mmHg) but this pressure in the other groups will regulated on 15 mmHg . group III: will receive ۳۰ mg IV ketorolac during surgery group IV:receive local intra-peritoneal concoction of bupivacaine ۲۰ mg and dexamethasone ۸ mg on the site of removing gall bladder.

Main outcome variables

The effect of different interventions in pain prevention, dose of analgesic that needed after surgery ,duration of hospitalization and daily performance .

General information

Reason for update

change in number of participation and randomization method .

Acronym

IRCT registration information

IRCT registration number: **IRCT20221129056662N1**

Registration date: **2022-12-13, 1401/09/22**

Registration timing: **prospective**

Last update: **2023-02-16, 1401/11/27**

Update count: **1**

Registration date

2022-12-13, 1401/09/22

Registrant information

Name

Halimeh Gohareyan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-14, 1401/09/23

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain preventive effects of different surgical techniques (low-pressure laparoscopy, intra operative ketorolac, and local bupivacaine administration) in female undergoing laparoscopic cholecystectomy.

Public title

Evaluation the pain prevention effect of different surgical techniques in laparoscopic cholecystectomy .

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pt should be female . Age 18 - 65 BMI 18/5 - 30 ASA score I or II Score that received from pain catastrophizing questionnaire should be less than 30 . Patient should be without any underlying disease . Patient should be interested to participate in the study and complete the informed consent .

Exclusion criteria:

Patient is a smoker . Patient take opium or opium component recently . Enable to speak in Persian . emergency surgery . Previous history of hepatobiliary surgery . Age less than 18 or more than 65 . patients that is male . Body mass index less than 18/5 or more than 30 . Patients with underlying disease like HTN , DM and other . Patients with chronic diseases like liver failure , renal failure , respiratory disease , heart problem and other . Addiction to tobacco or alcohol . Addiction to special drug .

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will randomly be divided into four groups, The randomization will be done by an independent external researcher .Randomization will be done by Excel .

Blinding (investigator's opinion)

Double blinded

Blinding description

After takking informed consent, patients are randomly allocated into four groups . patients wont be informed about allocation . data collector and data assessor are unaware of allocation . Only the surgeon knows allocation .

Placebo

Not used

Assignment

Parallel

Other design features

This is a double blinded RCT .

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Ilmam Hossein Sqe . Medical science university

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

IR.SUMS.MED.REC.1401.496

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

laparoscopic cholecystectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

This study is designed to evaluate the effect of pain prevention effect of different surgical technique in post op pain of laparoscopic cholecystectomy. these effects will be evaluated according to score that patients get from pain questionnaire .

Timepoint

patients complete the pain questionnaire in first follow up visit. this is 7 days after discharging from hospital .

Method of measurement

pain questionnaire

2**Description**

patient ' s daily performance

Timepoint

patients completed daily performance questionnaire at the first follow up visit . this visit will be 7 days after discharging .

Method of measurement

daily performance questionnaire

Secondary outcomes**1****Description**

dose of analgesic

Timepoint

during discharge from hospital .

Method of measurement

physician 's order that prescribed during hospitalization .

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

Intervention group: All the participants in this trial will go under laparoscopy with CO₂ pressure of 10 mmHg except this group. This experimental group will experience a 12 mmHg intra-abdominal CO₂ pressure .

Category

Treatment - Surgery

2**Description**

Intervention group: The patients who would be allocated in this group will receive a concoction of bupivacaine 2 . mg(local anesthesia) and dexamethasone 1 mg. mixture will be rubbed on the site of the removed gall bladder before the termination of the operation.

Category

Treatment - Drugs

3**Description**

Intervention group: Participants in this group will receive a single 30 . mg IV ketorolac just before the surgery ends.

Category

Treatment - Drugs

4**Description**

Control group: these patients will get standard protocol of laparoscopic surgery . all of participators will under go laparoscopic cholecystectomy with four-port technique .

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Namazi hospitl

Full name of responsible person

Hosseinie - Babak

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Namazi Sq , District 1, Shiraz

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2**Recruitment center****Name of recruitment center**

Hafez hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Memarpour- Mahtab

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Babak Hosseine

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Latest degree

Subspecialist

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

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Position

Medical student

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A Level or less

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

The data will be published after collection without mentioning personal data.

When the data will become available and for how long

After completing the study, the data will be accessible.

To whom data/document is available

The data will be accessible for researchers .

Under which criteria data/document could be used

Using the results for planning and conduct additional research .

From where data/document is obtainable

babak۱۳۸۰@gmail.com halimehg1378@gmail.com
xalirezasadeghix@gmail.com

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

1month

Comments