Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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.patiens 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

Country

Iran (Islamic Republic of)

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+98 71 5322 0974

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halimehg1378@gmail.com

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 Co۲ pressure of ۱۵ mmHg except this group. This experimental group will experience a ۱۲ mmHg intra-abdominal CO۲ pressure .
Category
Treatment - Surgery

2

Description
Intervention group: The patients who would be allocated in this group will receive a concoction of bupivacaine ۲۰ mg(local anesthesia) and dexamethasone ۸ 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 ۳۰ 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
Street address
Namazi Sq ، District 1، Shiraz
City
Shiraz
Province
Fars
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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
Street address
Zand Ave ، Central bluiding of Shiraz medical university
City
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7134814336
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
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
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Other areas of specialty/work
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Person responsible for updating data

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General Surgery
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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