Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Laparoscopic cholecystectomy Postoperative pain relief study by comparing four methods interpersonal instillation of normal saline, ropivacaine, sodium bicarbonate and ropivacaine-sodium bicarbonate combination

Protocol summary

Study aim
Laparoscopic cholecystectomy Postoperative pain relief study by comparing four methods of intraperitoneal instillation of normal saline, ropivacaine, sodium bicarbonate, and ropivacaine-sodium bicarbonate combination.

Design
An interventional and factorial (or replacement) study will be conducted in four groups of 50 with a sample size of 200, double-blind and randomized in completely separate groups.

Settings and conduct
In this study, 200 patients in 4 groups of 50 will be subjected to laparoscopic cholecystectomy in Shahid Faqihi and Abu Ali Sinai hospitals in Shiraz by the double-blind clinical trial method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent; Patients aged 18 to 60 are candidates for laparoscopic cholecystectomy. Exclusion criteria: history of heart diseases; High and low blood pressure; Bradycardia; 1st, 2nd, 3rd-degree heart block; Patients who use adrenoceptor agonist and antagonist drugs.

Intervention groups
Intervention group1:(A)will receive a dose of 10 ml of ropivacaine 0.5% (Made by Fresenius Kabi, Austria)in the areas below the right and left diaphragm and in the gallbladder, and intervention group 2: (B)will receive a dose of 10 ml of ropivacaine 0.5% along with sodium bicarbonate solution. With a dose of 50 ml, they will receive 7.5% in 1000 ml of normal saline at 37C. Intervention group 3: (C) will undergo intraperitoneal washing with 7.5% sodium bicarbonate solution and normal saline. Intervention group 4 (control group) (D) will be subjected to intraperitoneal washing with normal saline solution in 1000 ml.

Main outcome variables
post-operative pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180922041084N7**
Registration date: **2022-09-07, 1401/06/16**
Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**
Update count: **0**

Registration date
2022-09-07, 1401/06/16

Registrant information
Name
Maryam Tabibzadeh
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-09-21, 1401/06/30
Expected recruitment end date
2023-04-19, 1402/01/30
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Laparoscopic cholecystectomy Postoperative pain relief study by comparing four methods interpersonal instillation of normal saline, ropivacaine, sodium bicarbonate and ropivacaine-sodium bicarbonate combination

Public title

Laparoscopic cholecystectomy Postoperative pain relief study by comparing four methods interpersonal instillation of normal saline, ropivacaine, sodium bicarbonate and ropivacaine-sodium bicarbonate combination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent People aged 18 to 60 are eligible candidates for laparoscopic cholecystectomy surgery

Exclusion criteria:

History of heart diseases Hypertension Bradycardia Simultaneous presence of peripheral neuropathy pregnant women Patients who are addicted to drugs and stimulants

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 200 patients were randomly divided into 25 blocks with a size of 8 for four groups using the permutation random block method. Blocking and allocating the sequence will be done to hide it by a person not involved in the research, employing identical non-transparent envelopes. Then, based on the obtained blocks and in the order of the allocation sequence, the drugs will be given to the patients. This study is double-blind. Total sample size = number of groups * repetition of the number of groups in each block * number of blocks And it has been blocked through the following site:https://www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, The drugs are prepared by an anesthetist who is unaware of how the study is conducted and delivered to the anesthesiologist in the operating room, who is also unaware of how the study is completed. In this way, the patient, the anesthesia resident, and the person who prepares the medicine are not aware of the study group's allocation and are blinded to the study.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-01-24, 1400/11/04

Ethics committee reference number

IR.SUMS.MED.REC.1400.569

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K82.9

ICD-10 code description

Disease of gallbladder, unspecified

Primary outcomes

1

Description

Postoperative pain

Timepoint

Times 0-1-2-4-8-12 and 24 hours after the operation

Method of measurement

VAS (Visual Analog Scale) & VRS(Verbal Rating Scale) numerical scoring scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: group A patients; will receive 10 ml of ropivacaine 0.5% (Made by the company Fresenius Kabi, Austria) in the areas below the right and left diaphragm and in the gallbladder bed.
Category
Treatment - Surgery

2

Description
Intervention group2: In group B, they will receive ropivacaine 0.5 with a dose of 10 ml along with sodium bicarbonate solution(Made by Sopa company Iran) with a dose of 50 ml of 7.5% in 1000 ml of normal saline at a temperature of 37 degrees Celsius.
Category
Treatment - Surgery

3

Description
Intervention group3: In group C patients, sodium bicarbonate solution with a dose of 50 ml of sodium bicarbonate 7.5 in 1000 ml of normal saline at 37 degrees Celsius for 2 to 5 minutes is used to wash the abdomen, and after 5 minutes the liquid will be suctioned.
Category
Treatment - Surgery

4

Description
Intervention group4: Group D, which will undergo intraperitoneal washing with normal saline solution in the amount of 1000 ml alone.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faqhihi Hospital
Full name of responsible person
Mina Bazrafkan
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is against our policy.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available