Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effectiveness of the Intraperitoneal Irrigation with tumescent solution on the intensity of postoperative pain in laparoscopic cholecystectomy patients

Protocol summary

Study aim
Determining the effectiveness of intraperitoneal washing with Tamosent solution on postoperative pain intensity in laparoscopic cholecystectomy patients

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, 25 samples in each group, which includes 10% dropout during the study, and the number of samples for each group is 27. Allocation of samples to intervention groups is done using 6 random blocks method

Settings and conduct
Patients with symptomatic gallstones who refer to Velayat hospital and are candidates for laparoscopic cholecystectomy according to the order of the patient's surgeon. In group A, the surgeon will inject 200 ml of Tamosent solution in the space below the diaphragm and the gallbladder area under the guidance of a camera. did In group B, at the end of the operation, 500 ml of 0.9% normal saline will be used to wash the surgical bed, the upper surface of the liver and the right half of the diaphragm.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients of any age, sex, or occupation who are diagnosed with symptomatic gallstones or chronic cholecystitis. Exit criteria: pregnant women, age <25 years and >70 years, emergency cholecystectomy, intraoperative injury to the intestine or bile duct, intraoperative bleeding, gangrenous or emphysematous cholecystitis, obstructive jaundice. , choledocholithiasis, coagulopathy, rupture of the gallbladder during surgery or damage to the common bile duct, cholangitis, pancreatitis, carcinoma of the gallbladder and its abnormalities, previous upper abdominal surgery, and patients with a history of abuse Drugs or alcohol.

Intervention groups
Intraperitoneal lavage with Tamosent solution (intervention group) and intraperitoneal lavage with normal saline alone (control group)

Main outcome variables
Severity of pain after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230607058402N1**
Registration date: **2023-08-23, 1402/06/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-23, 1402/06/01**
Update count: **0**

Registration date
2023-08-23, 1402/06/01

Registrant information

Name
Amirarad Mahmoudi

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
2023-07-01, 1402/04/10

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of the Intraperitoneal Irrigation with tumescent solution on the intensity of postoperative pain in laparoscopic cholecystectomy patients

Public title

Evaluation of the effectiveness of the Intraperitoneal Irrigation with tumescent solution on the intensity of postoperative pain in laparoscopic cholecystectomy patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with symptomatic gallstones or chronic cholecystitis

Exclusion criteria:

Pregnant women aged <25 years and >70 years emergency cholecystectomy jaundice intraoperative injury to the intestine or bile duct intraoperative bleeding gangrenous cholecystitis or emphysema obstructive jaundice choledocholithiasis coagulopathy gallbladder rupture during surgery or damage to the common bile duct cholangitis pancreatitis gallbladder carcinoma and its abnormalities previous upper abdominal surgery Unwillingness to participate in the study patients with a history of drug or alcohol abuse

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind randomized clinical trial that is conducted in patients with symptomatic gallstones who refer to educational-therapeutic centers in the province and are candidates for laparoscopic cholecystectomy according to the order of the surgeon. Using the method of random blocks (Balance block randomization), they are assigned to two treatment groups A and B, the balanced randomization method for the participants in the randomized controlled clinical trial study of intraperitoneal lavage with Tamosent solution (group A) and intraperitoneal lavage with normal saline alone (group B) on postoperative pain intensity in laparoscopic cholecystectomy patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Checklist information is provided by the secretary of the department in which people with national code are registered to the person responsible for 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, separated into intervention and control groups (which only the secretary of the department knows about). It is not known which washing method it received. 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

City

Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2023-08-19, 1402/05/28

Ethics committee reference number

IR.QUMS.REC.1402.125

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description
intensity of postoperative pain
Timepoint
Assessment of shoulder and abdominal pain intensity at 6, 12 and 24 hours during 24 hours after surgery
Method of measurement
Visual Analog Score (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intraperitoneal washing with Tamosent solution (group A): At the beginning of surgery and right after inflating the pneumoperitoneum and before any dissection of the gallbladder, the surgeon injects 200 ml of Tamosent solution (a mixture of 5 ampoules of 0.5% bupivacaine and one vial of 7.5% sodium bicarbonate in 450 ml of normal Saline) will be injected in the space under the diaphragm and the gallbladder area with the guidance of the camera. The patient was kept in the Trendelenburg position for 5 to 10 minutes. After that, the patients will be placed in the anti-Trendelenburg position to start the surgery, and the laparoscopic operation will be performed in a standard way, and the rest of the serum containing the Tamosent solution will be injected during the surgery and at the end of the operation.
Category
Treatment - Drugs

2

Description
Control group: Intraperitoneal lavage with normal saline alone (group B): After placing the laparoscopic ports, the patients will be placed in the anti-Trendelenburg position to start the surgery, and the laparoscopic operation will be performed in a standard way, and at the end of the operation, 500 ml of 0.9% normal saline will be used to wash the upper surface of the liver and below the surgical bed. A semi-right aperture will be used. After the removal of the gallbladder is completed in both groups, fluids will be completely aspirated before the pneumoperitoneum is drained. At the end of the surgery, CO2 is carefully drained by manually compressing the abdomen with open trocars (especially through the epigastric trocar) and the drain will not be used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Amirarad Mahmoudi
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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
Amirarad mahmoudi

Position
Resident

Latest degree
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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