Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Effect of intraperitoneal irrigation with Ketamine in comparison with lidocaine on Pain following laparoscopic cholecystectomy, a randomized clinical trial

Protocol summary

Study aim

Reducing postoperative pain and improving general condition of patients after laparoscopic cholecystectomy

Design

In this study, patients will be divided into three groups by block randomization and interventions will be done at the end of the operation. The severity of the pain in the shoulders and also in the abdomen and in the upper right quadrant during the specified hours is evaluated and recorded. Additional analgesics requested by the patient will also be checked at specific hours and recorded in the questionnaire.

Settings and conduct

The study will be conducted in the operating room and surgery department of the Semnan Kosar Hospital(Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with chronic cholecystitis candidate for elective laparoscopic cholecystectomy
Exclusion criteria: 1. Using any drug that can affect on postoperative pain. 2. Addiction to drugs or alcohol (in the past or at present). 3. The presence of acute cholecystitis or empyema of the gallbladder. 4. Presence of severe inflammation and adhesion at the site of surgery so that open surgery is required. 5. Rupture of the gallbladder and bile leakage at the site of surgery. 6. Intraoperative bleeding so that resulted in peritoneal stimulation due to presence of blood in the peritoneum .

Intervention groups

In the first group of patients, the Surgical Site Irrigation will done by 100 cc normal saline 0.9% containing 3 mg / kg Lidocaine 1% for 5-10 minutes. In the second group of patients, the Surgical Site Irrigation will done by 100 cc of 0.9% saline solution containing 0.5 mg / kg of ketamine for 5 to 10 minutes. In the third group, the Surgical Site Irrigation will done by 100 ml of normal saline for 5 to 10 minutes. Then in each of the three groups, the fluid in the surgical site is suctioned as far as possible and at the end of the surgery the peritoneal air will be suctioned and the air in the posterior area of the liver is also actively suctioned.

Main outcome variables

Severity of Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N6**
Registration date: **2018-02-27, 1396/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-27, 1396/12/08**
Update count: **0**

Registration date

2018-02-27, 1396/12/08

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-06-09, 1397/03/19

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of intraperitoneal irrigation with Ketamine in comparison with lidocaine on Pain following laparoscopic cholecystectomy, a randomized clinical trial

Public title
Effect of Ketamine and lidocaine on Pain following laparoscopic cholecystectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Chronic Cholecystitis Candidate for elective Laparoscopic Cholecystectomy
Exclusion criteria:
Presence of severe inflammation and adhesion at the site of surgery so that laparoscopic surgery is not possible.
Rupture of the gallbladder and bile leakage at the site of surgery
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be entered into one of the three groups by block randomization method (6-blocks).
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient, person who assessing pain and data analyst are not aware of the patient's group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee, Semnan University of Medical Sciences
Street address
Basidj Boulevard
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2016-10-01, 1395/07/10
Ethics committee reference number
IR.SEMUMS.REC.1395.94

Health conditions studied

1

Description of health condition studied
Post Operative pain
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Severity of Pain
Timepoint
Every 1 hour up to 24 hours after surgery
Method of measurement
VAS: Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Surgical Site Irrigation will done by 100 cc normal saline 0.9% containing 3 mg / kg Lidocaine 1% for 5-10 minutes.Then all the fluid in the surgical site is suctioned as far as possible and at the end of the surgery the peritoneal air will be suctioned and the air in the posterior area of the liver is also actively suctioned.
Category
Treatment - Drugs

2

Description
Intervention group 2: In the second group of patients, the Surgical Site Irrigation will done by 100 cc of 0.9% saline solution containing 0.5 mg / kg of ketamine for 5 to 10 minutes.Then all the fluid in the surgical site is suctioned as far as possible and at the end of the surgery the peritoneal air will be suctioned and the air in the posterior area of the liver is also actively suctioned.

Category
Treatment - Drugs

3

Description
Control group: In the third group, the Surgical Site Irrigation will done by 100 ml of normal saline for 5 to 10 minutes.Then all the fluid in the surgical site is suctioned as far as possible and at the end of the surgery the peritoneal air will be suctioned and the air in the posterior area of the liver is also actively suctioned.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Saeedeh Ataei

Street address
Basidj Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan 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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Dr. Hamid Reza Hemmati

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

Contact

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Position
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Person responsible for updating data

Contact
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Semnan University of Medical Sciences
Full name of responsible person
Mehrdad Zahmatkesh
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Latest degree
Bachelor
Other areas of specialty/work
Others
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Results of statistical Analysis
When the data will become available and for how long
After completing the project
To whom data/document is available
Only the study researchers and Referee
Under which criteria data/document could be used
For similar studies
From where data/document is obtainable
Dr Hamid Reza Hemmati
What processes are involved for a request to access data/document
Calling and Email
Comments