

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asgari

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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

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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

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

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researcher

Latest degree

Bachelor

Other areas of specialty/work

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