Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigate the Effect of Interaperitoneal ketamin plus bupivacaine administration for pain relief laparascopic cholecystectomy and comparison with bupivacaine alon

Protocol summary

Study aim

Comparison of postoperative pain intensity in the studied groups 2) Comparison of the use of painkillers in the studied groups 3) Check and compare blood pressure in the studied groups before and after the intervention4) Examination and comparison of heart rate in the studied groups before and after the intervention5) Investigation of nausea and vomiting in the studied groups after the intervention6) Check the time required for painkillers in the studied groups after the intervention

Design

Study of clinical trial of two randomized double-blind sockets with phase 1-2, which has a control group. The relationship between the groups is parallel.Ninety patients undergoing laparoscopic elective cholecystectomy were randomly divided into three groups with random allocation software

Settings and conduct

Peritoneal solutions are injected into the liver bed after the gallbladder is removed. For group one, a combination of bupivacaine and ketamine , for the second group bupivacaine and For the third group, saline is injected in equal volumes to evaluate the effect of these solutions on the shoulder pain with a VAS scale. This study was two-way blind that the study participant and the person registering the variables were unaware of the study.

Participants/Inclusion and exclusion criteria

Be Elective laparoscopic cholecystectomy Age between 18 and 65 years • Weight between 55 and 100 kg • The duration of surgery is less than two hours.

Intervention groups

in group one, the combination of ketamine and bupivacaine, and in the second group, only bupivacaine, and in the control group, normal saline is injected into the peritoneum, in the liver bed, after separation of the gallbladder.

Main outcome variables

Shoulder pain score after laparoscopic surgery on Visual Analog Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047418N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Parvin Ziaiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3265 3741

Email address

p.ziaiei@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

2019-12-01, 1398/09/10

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-05, 1398/12/15

Scientific title

Investigate the Effect of Interaperitoneal ketamin plus bupivacaine administration for pain relief laparascopic cholecystectomy and comparison with bupivacaine alon

Public title

Evaluation of the effect of ketamine and bupivacaine combination on shoulder pain after gallbladder surgery by laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

elective laparascopic cholecystectomy age 18 -65 year weight 55-100 kg The duration of surgery is less than two hours. No neurovascular disease, coagulation disorders, cardiovascular disease • No history of ketamine and bupivacaine allergy No history of abdominal surgery

Exclusion criteria:

use of alcohol, painkillers and anti-inflammatory and non-steroidal anti-inflammatory drugs Having chronic pain unrelated to gallbladder disease Dissatisfaction of the patient to continue participating in this study he need for laparotomy during laparoscopy having acute cholecystitis People who could not understand VAS.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple randomization, numbers 1-30 were considered for group one intervention, numbers 31-60 for group tow intervention, and numbers 61-90 for group three intervention were considered. Using computer software, sequences of random numbers were creat in the numerical range 1-90. The numbers were recorded and assigned to one of the three groups based on the numerical range defined by each group. hen a card was prepared according to the number of samples and on them was written one of the numbers 1,2,3 that represented the type of group. Based on the created sequence, the card for each group was placed in similar envelopes and arranged in a box. In order to maintain a random sequence, numbering was performed on the outer surface of the envelopes, respectively. fter obtaining the patient's consent, one of the letters was opened and the patient's group was identified based on the card number. The random allocation was hidden by the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

An evaluator of study variables is the ward nurse who was unaware of the type of study and the subject of the study as well as the type of medication the patients received. Patients were unaware of their group and the medication they should receive And they were told that they were in one of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

no have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Health, Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Alam Square,. Shahid Sadoughi University of Medical Sciences Campus,. Yazd - Faculty of Health.

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.SSU.SPH.REC.1398.046

Health conditions studied

1

Description of health condition studied

Shoulder pain after laparoscopic surgery

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

The severity of shoulder pain after laparoscopic surgery

on (Visual Analogue Scale)

Timepoint

Two, four, six, eight hours after surgery

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

1

Description

Hypotension, pressure drop above 20% initial value

Timepoint

An hour before surgery and two, four, six, eight hours after laparoscopic cholecystectomy

Method of measurement

By a sphygmomanometer

2

Description

Number of heartbeats

Timepoint

An hour before surgery and in 2-4-6-8 hours after surgery

Method of measurement

By counting the number of pulses per minute that is recorded in the checklist.

3

Description

Dosage of analgesics

Timepoint

8 hours after surgery

Method of measurement

Using a syringe, it is registered in the checklist in milligrams.

4

Description

The first time analgesics are needed

Timepoint

8 hours after surgery.

Method of measurement

It is registered in the checklist and based on the minute.

5

Description

nausea and vomiting

Timepoint

2-4-6-8 hours after surgery

Method of measurement

View and ask .By options has and does not have in the checklist

Intervention groups

1

Description

Intervention group: In this group, 10 cc of bupivacaine 0.5% is combined with 0.5 mg / kg of ketamine, and with a normal saline of 0.9%, the volume of the drug reaches 20 cc.The compound is injected into the peritoneum at the end of the surgery and after the gallbladder is removed.

Category

Prevention

2

Description

Intervention group: In the second group, 10 cc of bupivacaine 0.5% with 10 cc of normal saline 0.9%, reaches a volume of 20 cc, and at the end of surgery and after removing the gallbladder, is injected into the peritoneum at the site of surgery.

Category

Prevention

3

Description

Control group: 20 cc of normal saline is injected into the peritoneum as a placebo at the end of surgery and after removal of the gallbladder.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Hossein Soleimani Salehabadi

Street address

Shahid Sadough Hospital ., Ibn Sina St., Shahid Ghandi Blvd., Safaieh

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Web page address

https://web.ssu.ac.ir/index.aspx?lang=1&sub=16

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person
Dr. Massoud Mirzaei

Street address
the central building of Yazd University of Medical Sciences., Bahonar Square

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Postal code
8916978477

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+98 35 3724 0171

Email
info@ssu.ac.ir

Web page address
https://web.ssu.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Parvin Ziaiei

Position
University Student

Latest degree
Bachelor

Other areas of specialty/work
Others

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Person responsible for scientific inquiries

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Specialist

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have not been identified.

When the data will become available and for how long

Start the course after publishing the results

To whom data/document is available

For researchers at academic and scientific institutions

Under which criteria data/document could be used

The applicant's academic resume is required.

From where data/document is obtainable

They can contact us by email: p.ziaiei@ssu.ac.ir

What processes are involved for a request to access data/document

The person receives the data by sending his / her scientific resume for a maximum of 3 months.

Comments