

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The effect of ketamine and oxytocin on postoperative pain control in patients undergoing elective laparoscopic gallbladder surgery

Protocol summary

Study aim

Determining the effect of ketamine and oxytocin in comparison with pethidine on postoperative pain control in patients candidates for cholecystectomy referred to Shohada-e-Ashayer and Rahimi hospitals

Design

Patients were divided into 3 groups (2 intervention group and one control group) by random number table. The first group was prescribed 0.5 units per kilogram of patient weight oxytocin and ketamine 0.5 mg per kilogram of patient weight after extubation. The second group received 0.5 mg of pethidine per kg body weight. And the third group, the control group, without intervention Ondansetron 4 mg and sufentanil 5 µg were administered equally to all patients after extubation. The patient's pain was assessed based on VAS 30 minutes after recovery, 1 and 2 hours after surgery

Settings and conduct

This study was performed on patients referred to Shohada-e-Ashayer and Shahid Rahimi Hospitals of Lorestan University of Medical Sciences. Blindfolding is performed on all patients, collecting and analyzing data

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients in the age range of 30-60 years who have no underlying (ASA class I) and pulmonary problems and no history of chronic pain after surgery. Exclusion criteria are all patients with a history of chronic pain and patients with specific drug dependence such as opium and patients with a history of psychiatric illness

Intervention groups

The first group received ketamine and oxytocin. The second group received pethidine. The third group is the control group.

Main outcome variables

Pain, nausea, blood pressure, heart rate, arterial oxygenation, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210108049969N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **retrospective**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Maryam Baghizadeh baghdashti

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 3323 6401

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-14, 1398/09/23

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ketamine and oxytocin on postoperative pain control in patients undergoing elective laparoscopic gallbladder surgery

Public title

The effect of ketamine and oxytocin on pain control, nausea, blood pressure, heart rate, satisfaction, postoperative blood oxygen saturation in patients undergoing elective laparoscopic gallbladder surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 30-60 years who have undergone laparoscopic cholecystectomy No pulmonary disease ASA class 1(American Society of Anesthesiologists) is a system for assessing the fitness of patients before surgery No history of chronic pain after surgery

Exclusion criteria:

History of chronic pain Specific drug dependence such as opium History of psychiatric illness

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table Random number table Table of Random Numbers A set of masses of Numbers that are produced without a specific pattern or order and in a completely random manner and are in the form of a table. In order to use a random number table, the researcher must first preset the table to read the numbers (for example, up, down, left, or right (the researcher's second assumption is to consider numbers for different groups), for example, even numbers for intervention. A and odd numbers for Intervention B, another method of taking the number 0-40 for intervention A and the number 41-80 for Intervention B is the numbers 120-181 for group C, then the researcher touches one of the numbers and moves in one of the predetermined directions and records the numbers and Allocates different groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

All blind people only know that participants are divided into 4 groups, but do not know the type of treatment intervention in each group to control pain, nausea, hemodynamic changes such as blood pressure and heart

rate, arterial oxygenation and patient satisfaction, and assign patients in 4 groups. It was done completely randomly through a table of random numbers, which is described as how to do it.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Moallem St., Shahid Anoushirvan Rezaei Sq., University of Medical Sciences

City

Khoram-Abad

Province

Lorestan

Postal code

6813833946

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.LUMS.REC.1398.226

Health conditions studied

1

Description of health condition studied

Status and comparison of pain after laparoscopic cholecystectomy in 3 study group

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Status and comparison of nausea after laparoscopic cholecystectomy in 3 study group

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Status and comparison of hemodynamic changes (blood pressure, heart rate, blood oxygenation) after laparoscopic cholecystectomy in 3 study group

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score based on visual analogue scale

Timepoint

After surgery in the recovery room, 1 and 2 hours after surgery

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving 0.5 mg of ketamine per kg of patient weight and oxytocin 0.5 units per kg of patient weight immediately after patient extubation. All of the following were similar in all three groups: Time Operation 1 - 2 Hour, drugs used during surgery (for premedication of fentanyl 1-2 micrograms per kilogram - Midazolam 0/05-0/15mg per kg body weight - Atracurium 0/5mg per kg Kg patient weight, propofol 1.5-2/5 mg / kg body weight, under isoflurane 1/2% inhalation anesthesia as maintenance anesthetic, similar serum therapy

Category

Rehabilitation

2

Description

Intervention group: Receiving 0.5 mg of pethidine per kg of patient weight is prescribed immediately after the patient's extubation. All of the following were the same in all three groups: time of operation 1-2 hour, intraoperative drugs (for premedication from Fentanyl 1-2 micrograms per kilogram - Midazolam 0/05-0/15 milligrams per kilogram body weight - Atracurium 0.5 mg per kilogram patient weight, Propofol 1.5-2.5 mg Per kilogram of body weight, under inhaled anesthesia with iso-fluorine 1/2 % as maintenance anesthetic, similar serum therapy

Category

Rehabilitation

3

Description

Control group: Do not receive medication, however, each group was prescribed 4 mg of ondansetron and 5 micrograms of sufentanil after extubation.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye- Ashayer Hospital

Full name of responsible person

Maryam Baghizadeh Baghdashti

Street address

Enqelab Ave, Shohadaye- Ashayer Hospital

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Recruitment center

Name of recruitment center

Shahid-Rahimi Hospital

Full name of responsible person

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Azadi Square, not far from Safavid Bridge, Shahid Rahimi Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Arash Karimi

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Moallem St., Shahid Anoushirvan Rezaei Sq., University of Medical Sciences

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Grant name

Grant code / Reference number

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

No

Title of funding source

Arash karimi-maryam baghizadeh

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Maryam Baghizadeh Baghdashti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Privacy of the patients

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

Results can be shared after Unidentifiablation people

When the data will become available and for how long

Access period starts, 6 months after the results are published

To whom data/document is available

کلیه افراد

Under which criteria data/document could be used

For the use of other researchers with the permission of the supervisor and the approval of the research assistant

From where data/document is obtainable

M.baghizadeh65@gmail.com

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

After obtaining the above items, the requested items will be sent

Comments