Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of low dose ketamine on postoperative pain, opioid consumption and hemodynamic changes in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Evaluation of the effects of low dose ketamine on postoperative pain, opioid consumption and hemodynamic changes in patients undergoing laparoscopic cholecystectomy

Design
Clinical trial with control group, simple randomization, 33 subjects in each group, with parallel groups, double blind

Settings and conduct
This study will be performed in the surgical ward of 5th Azar hospital in Gorgan. In this study, 66 individuals who need laparoscopic cholecystectomy surgery are randomly selected and after obtaining consent, before surgery incision (for laparoscopic trocar passage and blowing CO2), respectively in the intervention group and control group, 0.5 mg/kg ketamine and normal saline is injected as a bolus by the anesthesiologist assistant (ketamine and normal saline are equal in volume). The sampling method is simple randomization. The rate of postoperative pain (by VAS) and the amount and type of opioid administered within the first 24 hours after surgery are recorded in the checklist by the anesthesiologist. In this study, the anesthesiologist assistant is just aware of the type of injection (ketamine or normal saline).

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 60 years, the patients with Class 1 and 2 according to the American Society of Anesthesiologists (ASA1, 2), informed consent: Exclusion criteria: Abuse of drugs or opioids or psychotropic drugs, A history of seizures or taking anticonvulsants, Sensitivity to ketamine or anesthetic induction drugs, A history of high Intra cranial pressure (ICP), Patients with BMI≥40

Intervention groups
The intervention and control group: Respectively, injection of 0.5 mg/kg Ketamine and normal saline as a bolus (single injection) (both of them are similar in volume)

Main outcome variables
Postoperative pain, Opioid consumption, Hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170413033408N2**
Registration date: **2019-10-30, 1398/08/08**
Registration timing: **prospective**

Last update: **2019-10-30, 1398/08/08**
Update count: **0**

Registration date
2019-10-30, 1398/08/08

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3254 9891

Email address
dr.mojaveraghili@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-20, 1398/08/29

Expected recruitment end date
2020-02-18, 1398/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of low dose ketamine on postoperative pain, opioid consumption and hemodynamic changes in patients undergoing laparoscopic cholecystectomy

Public title

The effect of ketamine on pain relief after laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Class 1 and 2 physical activity according to the American Society of Anesthesiologists (ASA1, 2) who have completed the consent form Age range 18-60 years

Exclusion criteria:

Abuse of drugs or opioids or psychotropic drugs A history of seizures or taking anticonvulsants Sensitivity to ketamine or anesthetic induction drugs A history of high Intra cranial pressure (ICP) Patients with BMI≥40

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial selection will be unlikely and availability of the eligible patients.But the type of intervention is based on simple random sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups will be prescribed ketamine or placebo (normal saline) after anesthesia. To make the drugs unrecognizable to patients and researchers, they are both administered in an identical volume and format and are labeled A and B by the anesthesiologist assistant. Because the drugs are administered and administered by the anesthesiologist assistant, the outcome of the study will be measured and recorded by the anesthesiologist present in the recovery room who is unaware of the type of drug being administered.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-09-22, 1398/06/31

Ethics committee reference number

IR.GOUMS.REC.1398.186

Health conditions studied

1

Description of health condition studied

Patients with cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description

Postoperative pain

Timepoint

During the first 24 hours after surgery

Method of measurement

By Visual Analogue Scale (Score 1-10, 1=No pain, 10= worst pain)

2

Description

The amount of opioids consumption

Timepoint

During the first 24 hours after surgery

Method of measurement

The total dose of the drug administrated

3

Description
Changes in Systolic and diastolic blood pressure
Timepoint
After blowing gas into the peritoneal cavity and during the surgery
Method of measurement
Measurement of systolic and diastolic blood pressure by a barometer in millimeters of mercury (mmHg)

4

Description
Changes in mean arterial pressure
Timepoint
After blowing gas into the peritoneal cavity and during the surgery
Method of measurement
Mean arterial pressure in millimeters of mercury (mmHg), measured by systolic blood pressure and diastolic blood pressure by a barometer and calculate through Mean arterial pressure = systolic blood pressure + 2(diastolic blood pressure)/3

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After preparation of the surgical site and before surgical incision (for laparoscopic trochar passage and CO2 gas blowing), Ketamine is injected at a dose of 0.5mg/kg(Mfr.STEROP Belgium) as a bolus (single injection). Also, if the surgery lasts more than one hour in the target group, half the previous dose (0.25mg/kg) is used.
Category
Treatment - Drugs

2

Description
Control group: After preparation of the surgical site and before surgical incision (for laparoscopic trochar passage and CO2 gas blowing),placebo (normal saline) (in the same volume as ketamine) is injected as a bolus (single injection). Normal saline (in the same volume as ketamine) is also used in the control group if the operation lasts more than one hour. Normal saline is the brand name of normal saline solution which is containing 0.9% sodium chloride or 300 mOsm/L.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5th Azar hospital of Gorgan
Full name of responsible person
Seyed Babak Mojaver Aghili
Street address
5th Azar Avenue ,Gorgan, Golestan, Iran
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4917761551
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drbabaka35@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Reza Honarvar
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
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honarvar@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Seyed Babak Mojaver Aghili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology, Gorgan, Golestan, Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
Since 2022
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
No manipulation, mentioning the data reference
From where data/document is obtainable
Seyed Babak Mojaver Aghili, drbabaka35@gmail.com, Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology, Gorgan, Golestan, Iran.
What processes are involved for a request to access data/document
sending an email, complete the personal and professional characteristics with documentation
Comments