

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 CO<sub>2</sub>), 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 $\geq$ 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 $\geq$ 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

##### **City**

Gorgan

##### **Province**

Golestan

##### **Postal code**

4917761551

##### **Phone**

+98 17 3223 8363

##### **Email**

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

##### **City**

Gorgan

##### **Province**

Golestan

##### **Postal code**

49341-74515

##### **Phone**

+98 17 3253 8011

##### **Email**

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

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

**City**

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**Province**

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**Postal code**

49341-74515

**Phone**

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drbabaka35@gmail.com

## Person responsible for scientific 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

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## Person responsible for updating data

### 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

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**Postal code**

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**Phone**

+98 17 3253 8011

**Email**

drbabaka35@gmail.com

## 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**