

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Preventive effect of intramuscular ketamine and methadone on pain after laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

The Postoperative pain of laparoscopic cholecystectomy is one of the most common complications of this surgery. Analgesic drugs are commonly used to control this pain. Therefore, considering the importance of this issue, the current study aimed to examine the preventive effect of intramuscular ketamine and methadone on pain after laparoscopic cholecystectomy.

##### Design

90 patient candidates for laparoscopic cholecystitis surgery participated in this double-blind, randomized clinical trial study, with informed consent in Al-Zahra and Kashani hospitals in 2015-2017

##### Settings and conduct

Double-blind, randomized clinical trial study , 90 patents in Al-Zahra and Kashani hospitals in 2015-2017.

##### Participants/Inclusion and exclusion criteria

The entrance criterias included candidates for laparoscopic cholecystectomy, American Society of Anesthesiologists class 1 or class 2 (ASA), and the age between 18 and 75 years. Patients with a history of addiction to benzodiazepines or narcotics, including methadone, were not included in the study (exclusion criterion). If the duration of the surgery was longer (more than two hours), the surgical procedure was to be changed to laparotomy, a blood transfusion to the patient was required, or the type of anesthesia was to be changed, the patient would be excluded from the study

##### Intervention groups

The patient candidates were randomly divided into three groups. The first group received 1.5mg / kg ketamine, the second group received 0.15mg / kg methadone, and the third group received preoperative normal saline intra-muscularly

##### Main outcome variables

Hemodynamic changes, postoperative pain, the need for analgesic drugs, and the side effects of the procedure were investigated in the groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190127042511N1**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **retrospective**

Last update: **2019-12-13, 1398/09/22**

Update count: **0**

##### Registration date

2019-12-13, 1398/09/22

##### Registrant information

##### Name

Alireza Babaeizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3669 4561

##### Email address

alirezabbz@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2018-01-21, 1396/11/01

##### Actual recruitment start date

2016-01-21, 1394/11/01

##### Actual recruitment end date

2018-01-21, 1396/11/01

##### Trial completion date

2018-01-21, 1396/11/01

##### Scientific title

Preventive effect of intramuscular ketamine and methadone on pain after laparoscopic cholecystectomy

#### Public title

Preventive effect of intramuscular ketamine and methadone on pain

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

candidates for laparoscopic cholecystectomy  
ASA(American Society of Anesthesiologists) 1 or 2

##### Exclusion criteria:

Patients with a history of addiction to benzodiazepines or narcotics, including methadone

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **90**

Actual sample size reached: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Convenience sampling was done in these patients .the patients were randomly divided into three equal groups: ketamine, methadone, and control. Random Allocation Software was used to divide the patients into three groups randomly.It should be noted that the person who randomized the patients using the software was not aware of the conduction of the study.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The prescriber, statistical analyzer, and data collector were not aware of the types of groups and were blinded by the researcher

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Ethics committee of isfahan University of Medical Sciences

#### Street address

Hezarjerib ave

#### City

isfahan

#### Province

Isfahan

#### Postal code

#### Approval date

2016-01-10, 1394/10/20

#### Ethics committee reference number

IR.med.rec.1397.876

### Health conditions studied

#### 1

##### Description of health condition studied

Pain control after cholecystectomy Surgery

##### ICD-10 code

K80

##### ICD-10 code description

Cholelithiasis

### Primary outcomes

#### 1

##### Description

Pain score

##### Timepoint

5 min

##### Method of measurement

Visual analog scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group 1: One Intramuscular injection of 1.5mg per kg from 5 % Solution(50 mg in 1 ml) ketamin(Rotexmed co) before incision.injection site : deltoid muscle

##### Category

Prevention

#### 2

##### Description

Intervention group 2:One intramuscular injection of 0.15 mg per kg methadone from 0/5% Solution (5 mg in 1 ml) before incision.injection site : deltoid muscle

##### Category

Prevention

### 3

#### Description

Control group: One injection of same volume intramuscular sterile water before incision.injection site : deltoid muscle

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Alzahra hospital of isfahan

###### Full name of responsible person

Dr Gholamreza khalili

###### Street address

Shohada sofe

###### City

Isfahan

###### Province

Isfahan

###### Postal code

8174675731

###### Phone

+98 31 1668 5555

###### Email

Alzahra@med.mui.ac.ir

###### Web page address

http://alzahra.mui.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Gholamreza khalili

###### Street address

Hezar jerib

###### City

Isfahan

###### Province

Isfahan

###### Postal code

81746-73461

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###### Fax

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###### Email

med@med.mui.ac.ir

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

###### Full name of responsible person

Gholamreza khalili

###### Position

Associated professor

###### Latest degree

Specialist

###### Other areas of specialty/work

Anesthesiology

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Alireza babaei zadeh

###### Position

Resident of anesthesiology

###### Latest degree

Medical doctor

###### Other areas of specialty/work

Anesthesiology

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Tayeb

###### City

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###### Province

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza babaei zadeh

**Position**

Resident of anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Tayeb

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8136651856

**Phone**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

No - There is not 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