

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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		Ethics committee of isfahan University of Medical Sciences	
Public title	Preventive effect of intramuscular ketamine and methadone on pain	Street address	Hezarjerib ave
Purpose	Prevention	City	isfahan
Inclusion/Exclusion criteria		Province	Isfahan
Inclusion criteria:	candidates for laparoscopic cholecystectomy ASA(American Society of Anesthesiologists) 1 or 2	Postal code	
Exclusion criteria:	Patients with a history of addiction to benzodiazepines or narcotics, including methadone	Approval date	2016-01-10, 1394/10/20
Age	From 18 years old to 75 years old	Ethics committee reference number	IR.med.rec.1397.876
Gender	Both	Health conditions studied	
Phase	3	1	
Groups that have been masked	• Participant • Care provider • Outcome assessor • Data analyser	Description of health condition studied	
Sample size	Target sample size: 90 Actual sample size reached: 90	ICD-10 code	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
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.	Primary outcomes	
Blinding (investigator's opinion)	Double blinded	1	
Blinding description	The prescriber, statistical analyzer, and data collector were not aware of the types of groups and were blinded by the researcher	Description	
Placebo	Used	Timepoint	
Assignment	Parallel	Method of measurement	
Other design features		Secondary outcomes	
Secondary Ids	empty	Intervention groups	
Ethics committees		1	
1		Description	
Ethics committee		Category	
Name of ethics committee		2	
		Description	
		Category	

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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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