

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of the Effect of General Anesthesia with Opioids vs Opioid Free Anesthesia on Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy

#### Protocol summary

##### Study aim

Evaluate of postoperative pain both with and without Opioid general anesthesia technique in Laparoscopic Cholecystectomy

##### Design

In this study, 160 patients who were nominated for non-emergency Laparoscopic Cholecystectomy and who entered the study are referred to Kashan Shahid Beheshti Hospital. Participants are randomly divided into intervention and control groups and assigned a code to hide the intervention group of each participant.

##### Settings and conduct

This study is performed in the Department of Surgery of Shahid Beheshti Hospital of Kashan. Select the person code in each group is done by the Statistical Consultant, and Inclusion criteria and Exclusion criteria and the allocation of each patient according to the entry code are made by the Anesthetist's Assistant, but the anesthetist's process is conducted by the Senior Anesthetist Assistant. The persons evaluating the patient are different during surgery in Operating room, in the Recovery room, and in the Post-Surgical Department, and from the chosen anesthetic method for each patient are unaware, By doing this, Two-way blinding is provided in the study.

##### Participants/Inclusion and exclusion criteria

Age 18 - 65 years old, candidate for non-emergency Laparoscopic Cholecystectomy, ASA Class 1, 2. Exclusion criteria: Usage of Opioid Drugs within 24 hours before of surgery, Allergy to any medication used in the study, Motion Sickness, Addiction, Cardiac Disease, Hypertention, History of Sleep Apnea, Gastrointestinal Bleeding, Parkinson's disease, Liver and Kidney Diseases, Emergency Surgery, Pregnancy and BMI > 35.

##### Intervention groups

The first group will get Opioid-Free Anesthesia. Ketorolac, Ketamine, Lidocaine and Paracetamol will be used as an

alternatives of Opioid. The second group, fentanyl and Remifentanyl will be used. In both groups, hemodynamic changes are controlled with Nitroglycerin, Labetalol, Ephedrine and Atropine. Periodically, Meperidine, Paracetamol, Metoclopramide and Ondansetron will be prescribed if needed. BIS is maintained in the range of 40 to 60 during the anesthesia. The Meperidine and Paracetamol medications and Metoclopramide and Ondansetron are prescribed at intervals if needed.

##### Main outcome variables

Pain intensity and Nausea after surgery is measured by 11-item Visual Analog Scale.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171004036548N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

##### Registration date

2018-01-22, 1396/11/02

##### Registrant information

##### Name

Ahmad Haddad

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5542 0269

##### Email address

haddad-a@mail.kaums.ac.ir

**Recruitment status****Recruitment complete****Funding source**

Kashan University of Medical Sciences

**Expected recruitment start date**

2016-09-22, 1395/07/01

**Expected recruitment end date**

2017-09-23, 1396/07/01

**Actual recruitment start date**

2016-10-16, 1395/07/25

**Actual recruitment end date**

2017-10-20, 1396/07/28

**Trial completion date**

empty

**Scientific title**

Comparison of the Effect of General Anesthesia with Opioids vs Opioid Free Anesthesia on Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy

**Public title**

Comparison of the Effect of General Anesthesia with Opioids vs Opioid Free Anesthesia on Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 - 65 years old Candidate for non-emergency Laparoscopic Cholecystectomy ASA Class 1, 2

**Exclusion criteria:**

Use of Opioid drugs within 24 hours before surgery  
Allergy to any medication used in the study  
Motion sickness  
Addiction  
Cardiac disease, Hypertention  
History of Sleep Apnea  
Gastrointestinal bleeding  
Parkinson's disease  
Liver and Kidney Diseases  
Emergency surgery  
Pregnancy  
BMI > 35

**Age**From **18 years** old to **65 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**Target sample size: **160**Actual sample size reached: **160****Randomization (investigator's opinion)**

Randomized

**Randomization description**

After referral of patients for elective Laparoscopic Cholecystectomy and evaluation of inclusion criteria and removal of patients who have exit criteria, they are divided into 2 groups using randomized block assignment (Permuted block randomization). The first group received an Opioid free anesthesia and the second

group received a routine anesthesia (with Opioid).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After admitting the patients, the Anesthetist's Assistant assesses them in terms of Inclusion Criteria and Exclusion Criteria., and then the Volunteers are selected from among them, and after obtaining Informed Written Consent from them, they are enrolled in the study without knowing the group in which they are placed. The Code assigned to each participant will be the order of Admission time. The position of each Code in the two groups is determined by the Statistics Consultant (Before commencing the admission of patients). The Anesthetic process is performed by the Senior Assistant and the Researcher does not play a direct role in the anesthetic process. Patient evaluators are different in the Operating Room and Recovery Room and Post-Surgical Ward, and are unaware of the anesthetic method. By doing this, Double-blind study method is provided.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

**Street address**

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Approval date**

2016-08-28, 1395/06/07

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1395.53

**Health conditions studied****1****Description of health condition studied**

Cholelithiasis

**ICD-10 code**

K80.1

**ICD-10 code description**

Calculus of gallbladder with other cholecystitis

## Primary outcomes

### 1

#### Description

Nausea

#### Timepoint

In recovery and 3,6,12,24 hour after surgery

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Intensity of pain

#### Timepoint

In recovery and 3,6,12,24 hour after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The second group: Conventional Anesthesia Method (with Opioid). The anesthesia will be administered by following drugs, including: Midazolam 0.03 mg/kg IV, Fentanyl 3 µ/kg, Propofol 2 mg/kg IV, Atracurium 0.5 mg/kg IV, Lidocaine 1.5 mg/kg IV, and Iso

#### Category

Treatment - Drugs

### 2

#### Description

First group: Opioid-free anesthesia. The anesthesia will be administered by following drugs, including: Midazolam 0.03 mg/kg IV, Propofol 2 mg/kg IV, Atracurium 0.5 mg/kg IV, Lidocaine 1.5 mg/kg IV, followed by 2 mg/kg/h, and Isoflurane 1.5%. Opioids will

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shaheed Beheshti Hospital

##### Full name of responsible person

Mohammad Reza Fazel

##### Street address

Qotb Ravandi Blvd., Shaheed Behshti Hospital

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715981151

##### Phone

+98 31 5554 0026

##### Fax

##### Email

beheshtihospital@kaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Gholam Ali Hamidi

##### Street address

Ghotbe Ravandi Blvd., Kashan University of Medical Sciences

##### City

kashan

##### Province

Isfahan

##### Postal code

8715988141

##### Phone

+98 31 5554 2999

##### Email

hamidi\_gh@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Ahmad Haddad

##### Position

Assistant

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

**Street address**

Ghotbe Ravandi Blvd., Shaheed Beheshti Hospital

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5542 0269

**Fax**

**Email**

Dr.ahmadhaddad@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Seyed Mohammad Reza Razavizadeh

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ghotbe Ravandi Blv.,Shaheed Beheshti Hospital

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5554 0026

**Fax**

**Email**

mr\_razavi48@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Ahmad Haddad

**Position**

Assistant Anesthesiologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ghotbe Ravandi Blvd

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Phone**

+98 31 5554 2999

**Fax**

**Email**

dr.ahmadhaddad@yahoo.com

**Web page address**

**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**

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

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable