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 Remifentanil 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 Mepridine 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
Isfehan
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
Nausa
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 Metod (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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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