Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the Effect of Opioid-sparing Anesthesia versus Opioid-based Anesthesia on Pain Intensity and Recovery Outcomes after Laparoscopic Surgery

Protocol summary

Study aim
To compare the analgesic efficacy and recovery profile of opioid-based anesthesia versus opioid-sparing anesthesia in adult patients undergoing elective laparoscopic surgery.

Design
A randomized controlled clinical trial, with parallel groups, double-blinded (patient and outcome assessor), phase 4, conducted on 100 patients (50 in each group). Randomization will be performed using a simple randomization method with a 6-faced die and a 1:1 allocation ratio.

Settings and conduct
patients will be allocated to OBA and OSA groups. On surgery day, anesthesia is given per group: OBA receives fentanyl, OSA receives ketamine, dexmedetomidine, and local anesthesia. Vital signs are recorded at set times. After surgery, patients go to PACU for 24-hour monitoring of pain, nausea, Aldrete score, opioid use, and adverse events. Patient satisfaction is also assessed. The study takes place at Al-Shatrah General Hospital, Dhi Qar, Iraq.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: -Age: Between 18 and 65 years (. -ASA Physical Status: Class I or II . Elective laparoscopic surgery -Ability to understand and sign informed consent: Exclusion Criteria: -ASA Physical Status Class III or higher. -History of allergy or contraindication to any drug used in either anesthetic technique. -Opioid abuse or chronic use of narcotics. -Significant cardiopulmonary, hepatic, or renal disease. -Pregnancy or lactation. -Cognitive impairment or psychiatric illness -BMI > 35 kg/m²

Intervention groups
Patients are divided into two groups. The first group receives standard opioid-based anesthesia, meaning opioids are used both during anesthesia and after surgery for pain control. The second group receives opioid-sparing anesthesia,

Main outcome variables
Postoperative pain intensity (NRS) at 0, 1, 2, 4, 6, 8, and 12 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260428069192N2**
Registration date: **2026-08-07, 1405/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-07, 1405/05/16**
Update count: **0**

Registration date
2026-08-07, 1405/05/16

Registrant information

Name
Mohamad Sorani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-02, 1405/05/11

Expected recruitment end date
2026-10-02, 1405/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Opioid-sparing Anesthesia versus Opioid-based Anesthesia on Pain Intensity and Recovery Outcomes after Laparoscopic Surgery

Public title

Opioid-free versus Opioid-based Anesthesia in Laparoscopic Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

AgeBetween 18 and 65 years (both sexes) Physical Status: Class I or II (American Society of Anesthesiologists classification) Elective laparoscopic surgery, including:Laparoscopic cholecystectomyGynecologic laparoscopic surgeryOther general laparoscopic procedures performed under general anesthesia Informed Consent: Ability to understand the study procedures and provide written informed consent

Exclusion criteria:

Physical Status Class III or higher History of allergy or contraindication to any drug used in either anesthetic technique Opioid abuse or chronic narcotic use Significant cardiopulmonary, hepatic, or renal disease Pregnancy or lactation Cognitive impairment or psychiatric illness that could compromise postoperative assessment Body Mass Index (BMI) > 35 kg/m² (if considered a confounding factor)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients meeting the inclusion criteria, following final confirmation of eligibility (which occurs after preoperative assessments and is typically determined 2–3 days prior to surgery), will be allocated to one of two intervention groups in a 1:1 ratio using simple randomization with a 6-faced die on the day of surgery, after patient transfer to the operating room, but prior to anesthesia induction. Accordingly, an individual independent of the research team will roll the die immediately after patient transfer to the operating room and before any therapeutic intervention, and based on the number shown, the patient will be randomly assigned to one of the two groups (numbers 1, 2, and 3 = Group A; numbers 4, 5, and 6 = Group B). The treatment team will be immediately informed of the patient's group assignment and will apply the anesthesia protocol and treatment regimen appropriate to the intervention or control group. The allocation of each patient will be performed entirely independently of previous allocations.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a full blind design is not feasible because the anesthesiologist must know which drugs to administer to the patient. Therefore, patient and outcome assessor blinding is applied: Patient (Blinded): The patient is unaware of their group assignment (whether they are receiving opioid-based anesthesia or opioid-sparing anesthesia). All drugs are administered in such a way that the patient cannot distinguish the difference. Outcome Assessor (Blinded): The personnel who record pain intensity, nausea and vomiting, Aldrete scores, and other outcomes in the recovery room and surgical ward are not informed of the patient's group. These individuals have no role in the anesthesia process and only collect data according to the study protocol. Anesthesiologist and Anesthesia Technician (Unblinded): These individuals are aware of the patient's group because they need to prepare and administer the appropriate drugs. However, they are not involved in outcome assessment or data analysis. Statistical Analyst (Blinded): The person or team performing the final data analysis will remain unaware of group assignments until the analysis is finalized. Data will be provided using numerical codes without group labels.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Public Health & Allied Medical Sciences- Tehran University o

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No. 17, Mohammad Ebrahim Bastani Parizi Alley, Qods Street, Enghelab Street, Enghelab Square, Tehran, Iran

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tehran

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1417744361
Approval date
2026-08-02, 1405/05/11
Ethics committee reference number
IR.TUMS.SPH.REC.1405.136

Health conditions studied

1

Description of health condition studied
complications of anaesthesia
ICD-10 code
T88.5
ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Postoperative Pain Intensity (NRS): atient-reported pain intensity on a numerical rating scale from 0 to 10 (0 = no pain, 10 = worst imaginable pain)
Timepoint
NRS score recorded at PACU arrival, 30 min, 1, 2, 4, 6, 12, and 24 hours postoperatively
Method of measurement
Numerical Rating Scale (0–10)Description: The patient reports their pain intensity on a scale from 0 (no pain) to 10 (worst imaginable pain).

Secondary outcomes

1

Description
Incidence of Adverse Events: Occurrence of any adverse event related to anesthesia or administered drugs during the first 24 hours after surgery
Timepoint
First 24 hours after surgery
Method of measurement
Clinical recording by a blinded assessor based on predefined criteria

2

Description
Intraoperative Hemodynamic Parameters: Changes in the patient's vital signs during surgery, including heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure
Timepoint
pre-induction- Post-induction - Post-intubation- 5 minutes after pneumoperitoneum- 30 minutes after pneumoperitoneum- After exsufflation (gas removal)- End of surgery (wound closure)- PACU Arrival15 minutes post-operation - 30 minutes post-operation - 60 minutes post-operation
Method of measurement
Recorded using standard hospital monitoring (electrocardiography, non-invasive blood pressure monitor, and pulse oximetry) at predefined time points

3

Description
Total opioid consumption in first 24 hours
Timepoint
The total amount of opioid consumption during the first 24 hours after surgery
Method of measurement
The total amount of opioid consumption (both as regular scheduled doses and as rescue medication) during the first 24 hours after surgery will be calculated in milligrams and recorded according to the type of opioid administered.

Intervention groups

1

Description
Intervention group(Opioid-Sparing Anesthesia): Induction Agent: Propofol 2–2.5 mg/kg 10 mg/mL concentration) administered intravenously.Alternative Analgesic for Induction: Low-dose ketamine 0.2–0.5 mg/kg (, 50 mg/mL concentration) administered intravenously (no fentanyl used during induction).Muscle Relaxant: Rocuronium 0.6 mg/kg (, 10 mg/mL concentration) administered intravenously to facilitate endotracheal intubation.Maintenance: Sevoflurane (1–2% concentration in a mixture of oxygen and air) along with a continuous infusion of dexmedetomidine (100 µg/2 mL concentration, diluted in normal saline) at a dose of 0.2–0.7 µg/kg/h using a syringe pump. If available per hospital protocol, lidocaine infusion (, 2% or 20 mg/mL concentration) is also added at 1–1.5 mg/kg/h.Local Anesthesia: Port-site infiltration with 0.25% bupivacaine () 10–15 mL before incision, or transversus abdominis plane (TAP) block with 0.25% bupivacaine if hospital protocol allows.Postoperative Pain Management: Intravenous paracetamol (10 mg/mL concentration) 1 gram every 6 hours, and non-steroidal anti-inflammatory drugs (e.g., intravenous ketorolac, Temad Pharmaceutical, 30 mg/mL concentration) 30 mg every 8 hours if no contraindication. Opioids (intravenous morphine 2–4 mg) are administered only as rescue medication in case of pain score of 4 or more on the Numerical Rating Scale.Duration of Intervention: All intraoperative medications are administered from induction until the end of anesthesia, and postoperative pain management continues for 24 hours after surgery.
Category
Treatment - Drugs

2

Description
Control Group) Opioid-Based Anesthesia): Induction Agent: Propofol 2–2.5 mg/kg (Farsus or Kasra

Pharmaceutical, 10 mg/mL concentration) administered as intravenous injection.Analgesic for Induction: Fentanyl 1–2 µg/kg (50 µg/mL concentration) administered as intravenous injection.Muscle Relaxant: Rocuronium 0.6 mg/kg (10 mg/mL concentration) administered intravenously to facilitate endotracheal intubation.Maintenance: Sevoflurane (1–2% concentration in a mixture of oxygen and air) along with additional fentanyl boluses 0.5–1 µg/kg if heart rate or blood pressure increases by more than 20% from baseline.Postoperative Pain Management: Intravenous paracetamol (10 mg/mL concentration) 1 gram every 6 hours, and if needed, intravenous morphine (10 mg/mL concentration) 2–4 mg as rescue medication in case of pain score of 4 or more on the Numerical Rating Scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Shatrah General Hospital in Dhi Qar Province, Iraq

Full name of responsible person

Mohamad Sorani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran University of Medical Sciences

Proportion provided by this source

10

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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Sorani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
All data will remain confidential in accordance with the ethical commitment, and only aggregated group-level results will be published in the form of a final article or report.

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Individual participant data will not be shared. The only publishable documents include the aggregated study results in the form of the final manuscript and the Statistical Analysis Plan (SAP). Study results will be disseminated through publication in a reputable national or international peer-reviewed journal in the field of anesthesiology, as well as presentation at relevant scientific conferences

When the data will become available and for how long
Access to SAP: immediately after IRCT registration. Access to aggregated results (manuscript): submitted within 12 months of data collection completion; publicly available 6 months post-publication

To whom data/document is available
IPD will not be shared. Aggregated results (manuscript) and SAP will be publicly and unrestrictedly available to all—academic researchers, industry professionals, students, and the public—via the publishing journal and IRCT.

Under which criteria data/document could be used
IPD will not be shared. For use of aggregated results and SAP: 1. Proper citation is mandatory. 2. Direct commercial use is not permitted. 3. Compliance with research ethics is required. 4. No formal request is needed due to open-access publication.

From where data/document is obtainable
Applicants, in order of priority: 1. Publishing journal website (manuscript). 2.. Principal investigator email . 3. PubMed, Scopus, and Google Scholar.

What processes are involved for a request to access data/document
En No application process. Immediate, free download from journal website or Email inquiries

Comments