Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

To compare the efficacy of propofol monotherapy versus propofol-ketamine combination on peri-extubation outcomes in patients undergoing laparoscopic cholecystectomy under general anesthesia

Protocol summary

Study aim
To compare the effect of propofol alone versus propofol-ketamine combination on peri-extubation quality and hemodynamic stability in patients undergoing cholecystectomy under general anesthesia.

Design
This will be a randomized, double-blind, active-controlled, parallel-group, phase 3 clinical trial conducted on 100 patients.

Settings and conduct
Randomized, double-blind clinical trial on 100 elective cholecystectomy patients at Al-Hussein and Bint Al-Hoda hospitals, Nasiriyah, Iraq. Two groups of 50: propofol alone vs. propofol-ketamine (simple randomization via Excel). Patient and data analyst blinded.

Participants/Inclusion and exclusion criteria
Inclusion: Age 18–65 years, ASA class I or II, elective cholecystectomy under general anesthesia, written informed consent. Exclusion: Severe cardiac/pulmonary/hepatic/renal/neurological disease, allergy to propofol or ketamine, psychiatric history/substance abuse, pregnancy/lactation, BMI >35, difficult airway, emergency surgery.

Intervention groups
Group Propofol alone: Induction with propofol 2 mg/kg IV; maintenance with continuous propofol infusion of 100–150 µg/kg/min Group Propofol–Ketamine combination: Induction with propofol 2 mg/kg IV + ketamine 0.5 mg/kg IV; maintenance with continuous propofol infusion of 100–150 µg/kg/min (no additional ketamine)

Main outcome variables
Primary outcomes: Extubation quality (5-point score: coughing, agitation, breath-holding, laryngospasm) and hemodynamic parameters (HR, SBP, DBP, MAP) at baseline, induction, intubation, extubation, and 0, 5, 15, and 30 minutes post-extubation.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260428069192N4**
Registration date: **2026-08-15, 1405/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-15, 1405/05/24**
Update count: **0**

Registration date
2026-08-15, 1405/05/24

Registrant information
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Mohamad Sorani
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-07-14, 1405/04/23
Expected recruitment end date
2026-10-07, 1405/07/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare the efficacy of propofol monotherapy versus propofol-ketamine combination on peri-extubation outcomes in patients undergoing laparoscopic cholecystectomy under general anesthesia

Public title
Investigating the Effect of Propofol-Ketamine Combination on the Quality of Emergence from Anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: Adults aged 18 to 65 years. ASA Physical Status: Classified as American Society of Anesthesiologists (ASA) physical status I or II. Surgical Procedure: Scheduled for an elective laparoscopic or open cholecystectomy under general anesthesia. Consent: Willing and able to provide written informed consent after understanding the study protocol.

Exclusion criteria:
Severe Underlying Diseases: Presence of severe cardiac, pulmonary, hepatic, renal, or neurological disorders. Drug Allergy: Documented hypersensitivity or contraindication to propofol or ketamine. Psychiatric History or Substance Abuse: A history of mental illness or substance abuse. Pregnancy and Lactation: Pregnant or lactating women. Morbid Obesity: Body mass index (BMI) exceeding 35 kg/m². Difficult Airway: Anticipated difficult airway based on standard pre-anesthetic assessments. Emergency Surgery: Requirement for urgent or emergency surgical intervention.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be divided into two equal groups using the simple randomization method. A random number sequence will be generated using statistical software (such as SPSS or Excel) via the random number function (RANDBETWEEN). Odd numbers will be allocated to Group 1 (Propofol alone) and even numbers to Group 2 (Propofol–Ketamine combination). The allocation sequence will be prepared by an independent colleague who is not involved in the data collection process. To ensure allocation concealment, the group codes will be placed in sequentially numbered, opaque, sealed envelopes. After obtaining written informed consent and upon the patient's arrival in the operating room, the corresponding envelope will be opened, and the assigned intervention will be administered

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind trial. The study drugs for both groups will be prepared by an independent colleague who is not involved in data collection, and will be provided to the anesthesiologist in identical, coded containers. The anesthesiologist will be aware of the drug composition due to the clinical necessity of knowing the type and dosage of the administered agent for safe anesthesia management. However, the patient will remain unaware of the treatment allocation, and the data analyst, who is responsible for the statistical analysis of the results, will remain blinded to the group codes until the completion of all analyses. Thus, blinding of the patient and the data analyst is maintained.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Public Health and Paramedical Sciences, Tehran University of Medic

Street address
School of Public Health, Tehran University of Medical Sciences (TUMS), Poursina St., Qods (Ghods) St., Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
141556446

Approval date
2026-07-14, 1405/04/23

Ethics committee reference number
IR.TUMS.SPH.REC.1405.124

Health conditions studied

1

Description of health condition studied
Laryngeal spasm

ICD-10 code
J38.5

ICD-10 code description

Laryngeal spasm

Primary outcomes

1

Description

Extubation quality score based on a validated 5-point scale comprising four domains: cough severity (none/mild/moderate/severe), agitation severity (none/mild/moderate/severe), breath-holding (present/absent), and laryngospasm (present/absent), assessed immediately after extubation

Timepoint

Measurement of the extubation quality score immediately after extubation. This assessment is performed at a single time point by the blinded outcome assessor

Method of measurement

Direct observation by a blinded assessor at the moment of extubation, using a validated 5-point scale (coughing, agitation, breath-holding, laryngospasm). Recorded in the Case Report Form

Secondary outcomes

1

Description

hypotension during Extubating

Timepoint

Incidence of hypotension, defined as a decrease in systolic blood pressure below 90 mmHg or a drop of more than 20% from baseline requiring pharmacological intervention. Measured using an automated non-invasive blood pressure (NIBP) cuff at baseline, induction, intubation, intraoperatively, extubation, and recovery. Recorded in the Case Report Form (CRF).

Method of measurement

Automated NIBP cuff at baseline, induction, intubation, intraoperatively, extubation, and recovery. Recorded in CRF.

2

Description

Continuous ECG monitoring at baseline, induction, intubation, intraoperatively, extubation, and recovery. Recorded in CRF

Timepoint

during extubating

Method of measurement

cardiac monitoring using hospital monitoring devices

Intervention groups

1

Description

Intervention group: Premedication consists of midazolam 0.03–0.05 mg/kg IV (manufactured by Tehran Shimi Pharmaceutical Company, brand: Midazolam Tehran Shimi) and fentanyl 1–2 µg/kg IV (manufactured by Exir Boroujerd Pharmaceutical Company, brand: Fentanyl Exir), administered 5 minutes before induction at the discretion of the anesthesiologist. Anesthesia is induced with propofol 2 mg/kg IV (propofol 1%, injectable emulsion, manufactured by Tehran Shimi Pharmaceutical Company, brand: T-Cifol) given as a slow bolus over 30–60 seconds, along with ketamine 0.5 mg/kg IV (manufactured by Exir Boroujerd Pharmaceutical Company, brand: Ketamine Hydrochloride Exir) administered simultaneously (either in a single syringe or in two separate syringes via two different IV lines, according to the anesthesiologist's discretion). To facilitate tracheal intubation, atracurium 0.5 mg/kg IV (manufactured by Iran Hormone Pharmaceutical Company, brand: Atracurium Iran Hormone) is administered. Anesthesia is maintained with a continuous IV infusion of propofol at 100–150 µg/kg/min (via syringe pump). In this group, no additional ketamine is administered unless clinically necessary (e.g., severe hypotension or inadequate depth of anesthesia), in which case ketamine 0.25–0.5 mg/kg IV will be given as a bolus by the anesthesiologist. If needed, supplemental doses of atracurium (0.1 mg/kg) are given to maintain muscle relaxation. Mechanical ventilation is performed with an oxygen–air mixture (FiO_2=0.5) using a volume-controlled ventilator, adjusted to maintain $EtCO_2$ within 35–45 mmHg. Hemodynamic parameters (blood pressure, heart rate, oxygen saturation) are continuously monitored throughout surgery. A decrease in mean arterial pressure >20% from baseline is treated with intravenous fluids or ephedrine (manufactured by Tehran Shimi Pharmaceutical Company, brand: Ephedrine Tehran Shimi), and bradycardia with atropine (manufactured by Tehran Shimi Pharmaceutical Company, brand: Atropine Tehran Shimi). At the end of surgery, the propofol infusion is discontinued and the patient is transferred to the recovery room. If pain is present, morphine 0.05–0.1 mg/kg IV (manufactured by Darupakhsh Pharmaceutical Company, brand: Morphine Sulfate Darupakhsh) is administered; if nausea occurs, ondansetron 4 mg IV (manufactured by Exir Boroujerd Pharmaceutical Company, brand: Ondansetron Exir) is given. All drugs are administered by the anesthesiologist via the intravenous route according to the department's standard protocol. The intervention duration is calculated from induction until the end of surgery

Category

Treatment - Drugs

2

Description

Control group: Premedication consists of midazolam 0.03–0.05 mg/kg IV (manufactured by Tehran Shimi Pharmaceutical Company, brand: Midazolam Tehran Shimi) and fentanyl 1–2 µg/kg IV (manufactured by Exir Boroujerd Pharmaceutical Company, brand: Fentanyl Exir), administered 5 minutes before induction at the discretion of the anesthesiologist. Anesthesia is induced with propofol 2 mg/kg IV (propofol 1%, injectable emulsion, manufactured by Tehran Shimi Pharmaceutical Company, brand: T-Cifol) given as a slow bolus over

30–60 seconds. To facilitate tracheal intubation, atracurium 0.5 mg/kg IV (manufactured by Iran Hormone Pharmaceutical Company, brand: Atracurium Iran Hormone) is administered. Anesthesia is maintained with a continuous IV infusion of propofol at 100–150 µg/kg/min (via syringe pump). If needed, supplemental doses of atracurium (0.1 mg/kg) are given to maintain muscle relaxation. Mechanical ventilation is performed with an oxygen–air mixture (FiO_2=0.5) using a volume-controlled ventilator, adjusted to maintain $EtCO_2$ within 35–45 mmHg. Hemodynamic parameters (blood pressure, heart rate, oxygen saturation) are continuously monitored throughout surgery. A decrease in mean arterial pressure >20% from baseline is treated with intravenous fluids or ephedrine (manufactured by Tehran Shimi Pharmaceutical Company, brand: Ephedrine Tehran Shimi), and bradycardia with atropine (manufactured by Tehran Shimi Pharmaceutical Company, brand: Atropine Tehran Shimi). At the end of surgery, the propofol infusion is discontinued and the patient is transferred to the recovery room. If pain is present, morphine 0.05–0.1 mg/kg IV (manufactured by Darupakhsh Pharmaceutical Company, brand: Morphine Sulfate Darupakhsh) is administered; if nausea occurs, ondansetron 4 mg IV (manufactured by Exir Boroujerd Pharmaceutical Company, brand: Ondansetron Exir) is given. All drugs are administered by the anesthesiologist via the intravenous route according to the department's standard protocol. The intervention duration is calculated from induction until the end of surgery.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Hussein Teaching Hospital, Nasiriyah, Iraq
Full name of responsible person
Azhar jameel shuaibth Al raheef
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Tehran University of Medical Sciences
Full name of responsible person
mohamad Sorani
Position
assistant professor
Latest degree
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Other areas of specialty/work
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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
It is decided that individual participant data will not be publicly shared, and only the results of aggregate analyses will be published in the final article. The main reason for this decision is to protect the confidentiality and privacy of the participants. It should be noted that the initial informed consent form did not include permission for the publication and sharing of personal data of the patients. However, upon formal request from the journal in which the article will be published, the raw data may be made available to the journal's reviewers or editors, after complete removal of all identifiable information (such as names, surnames, contact numbers, and any personal identifiers), and will only be presented with hospital codes that have been assigned to each patient from the beginning of the study. No public dissemination of personal data will take place.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
.
When the data will become available and for how long
.
To whom data/document is available
.
Under which criteria data/document could be used
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments