Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of the effects of total intravenous anesthesia (TIVA with propofol) versus inhalational anesthesia (Isufluran) on the incidence of emergence delirium based on gender differences in adults undergoing abdominal surjeries

Protocol summary

Study aim

To compare the effect of two anesthetic maintenance techniques (total intravenous anesthesia with propofol versus inhalational anesthesia with isoflurane) on the incidence and severity of postoperative delirium in adults undergoing abdominal surgery, and to evaluate the modifying role of gender.

Design

Randomized, double-blind, parallel-group, superiority clinical trial on 200 patients (100 per group). Randomization will be performed using balanced block randomization with concealed allocation.

Settings and conduct

Population & Sampling: Adults 18-65 undergoing abdominal surgery at Imam Khomeini Hospital, Ilam. Simple random sampling, stratified by gender. Patients allocated to two equal groups of 100: TIVA (propofol) vs. Inhalational (isoflurane). Blinding: Randomized, double-blind, parallel-group trial. Patients, outcome assessors (delirium via CAM-ICU), and data analysts are blinded to group allocation. An independent anesthesiologist administers the drugs. Setting: Post-Anesthesia Care Unit (PACU), Imam Khomeini Hospital, Ilam.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 18-65 and abdominal surgery candidate. 2. ASA I or II. 3. No cognitive/psychiatric, hepatic/renal, substance abuse, or drug allergy. Exclusion criteria: 1. Age <18 or >65. 2. ASA ≥III. 3. History of cognitive/psychiatric, hepatic/renal, substance abuse, or drug allergy.

Intervention groups

Group 1: total intravenous anesthesia with continuous propofol infusion (100–150 µg/kg/min) and fentanyl. Group 2: inhalational anesthesia with isoflurane (0.8–1.2 MAC) plus fentanyl. Anesthesia induction is identical in both groups using propofol, fentanyl, and atracurium.

Main outcome variables

Incidence of delirium , severity of delirium , time to extubation, length of stay in the recovery room, hemodynamic changes, and consumption of additional drugs.

General information

Reason for update

Acronym

TIGER-ED

IRCT registration information

IRCT registration number: **IRCT20260714070195N1**
Registration date: **2026-10-19, 1405/07/27**
Registration timing: **prospective**

Last update: **2026-10-19, 1405/07/27**
Update count: **0**

Registration date

2026-10-19, 1405/07/27

Registrant information

Name

Atiyeh Zolfaghari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-04-22, 1406/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of total intravenous anesthesia (TIVA with propofol) versus inhalational anesthesia (Isufluran) on the incidence of emergence delirium based on gender differences in adults undergoing abdominal surjeries

Public title

Comparison of the Effect of Propofol Anesthesia (TIVA) versus Isoflurane on the Incidence of Postoperative Delirium Based on Sex Differences in Adults Undergoing Abdominal Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 65 years Undergoing abdominal surgery with general Anesthesia ASA physical status class I or II

Exclusion criteria:

History of serious psychiatric illness Pre-existing cognitive disorders Hepatic or renal failure Substance abuse Hypersensitivity to study drugs (propofol, isoflurane, etc.) Pregnancy or lactation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Balanced Block Randomization Randomization unit: Individual (each patient is randomized separately) Stratification factors: No stratification is used in this study. Randomization tool: Random number table Sequence generation: Blocks with different permutations including (ABBA, ABAB, AABB, BBAA, BABA, BAAB) are created, where A represents the TIVA with propofol group and B represents the isoflurane group. Then, based on a random number table, the allocation sequence is determined to maintain group balance and blinding. Allocation concealment: The study drugs (propofol solution and isoflurane liquid) are prepared in identical containers without any label indicating the group and are provided to the anesthesiologist. Only the principal investigator has access to the randomization codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study uses a double-blind design. Blinding is implemented as follows: 1. Participants (Patients): Patients receive complete information about the study one day before surgery but are unaware of the type of anesthesia method assigned to them. 2. Anesthesiologist (Intervention provider): Although the anesthesiologist is aware of the administered drug, all drugs are prepared in identical containers without any group-identifying labels to minimize selection bias. 3. Surgeon: The surgeon is blinded to the anesthesia method. 4. Recovery room nurses (Clinical caregivers): Nurses responsible for patient care and assessment in the post-anesthesia care unit (PACU) are blinded to the group allocation. 5. Outcome assessors: Trained nurses who administer the CAM-ICU and CAM questionnaires for delirium assessment are completely blinded to the patients' group allocation. 6. Principal investigator: The principal investigator has access to the randomization codes but is not involved in outcome assessment. However, the codes will be used for final data analysis. 7. Data analyst: The individual performing statistical analysis is blinded to group allocation to prevent bias in data interpretation. 8. Allocation concealment: Study drugs (propofol solution and isoflurane liquid) are prepared in identical containers without any group-identifying labels and are provided to the anesthesiologist. Only the principal investigator has access to the randomization codes and is not involved in drug administration.

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences Research Ethics Committee

Street address

Salman farsi st

City

Eyvan

Province

Ilam

Postal code

6941914485

Approval date
2026-07-14, 1405/04/23
Ethics committee reference number
Ir.medilam.rec.1405.115

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Incidence of postoperative delirium (POD) diagnosed using the standardized NUDESC (Nursing Delirium Screening Scale) at multiple time points including the PACU period, as well as 6 and 12 hours after surgery. This tool consists of 5 key items assessing the presence or absence of delirium symptoms. The total score ranges from 0 to 5, and a score of 2 or higher (NUDESC ≥ 2) is considered a positive diagnosis of delirium.
Timepoint
Delirium assessment using the NUDESC tool is performed at five time points:1. Upon admission to the PACU (immediately after transfer from the operating room)2. 30 minutes after PACU admission3. At the time of PACU discharge (when discharge criteria are met)4. 6 hours after surgery (in the ward)5. 12 hours after surgery (in the ward)
Method of measurement
Assessment is performed by trained and blinded nurses using the standardized NUDESC tool. The nurse, through direct patient observation, medical record review, and interview with the patient's companion (if necessary), evaluates the presence or absence of each of the following 5 signs:1. Disorientation2. Inappropriate behavior3. Inappropriate communication4. Hallucination/Delusion5. Psychomotor retardation/agitationEach sign scores 1 point, and the total score ranges from 0 to 5. A score of ≥ 2 is considered a positive diagnosis of delirium.Simultaneously with delirium assessment at these time points, hemodynamic parameters including Mean Arterial Pressure (MAP), Heart Rate (HR), and Arterial Oxygen Saturation (SpO_2) are also recorded and evaluated to assess the relationship between hemodynamic changes and the occurrence of delirium.

Secondary outcomes

empty

Intervention groups

1

Description
In this group, Total Intravenous Anesthesia (TIVA) is performed using Propofol. The induction dose of Propofol is administered intravenously at [exact number] mg/kg. For maintenance of anesthesia, a continuous infusion of Propofol is set at [exact number] mcg/kg/min. Propofol manufactured by [Company Name], with a concentration of 1% (10 mg/ml), will be used.
Category
Treatment - Drugs

2

Description
In this group, inhalation anesthesia is performed using Isoflurane. Induction of anesthesia is performed via a face mask or after tracheal intubation. Isoflurane is administered to the patient through the anesthesia machine at a concentration of [exact number] MAC. For maintenance of anesthesia, the Isoflurane concentration is set at [100]%. Isoflurane manufactured by [Abbott India limited], with a concentration of [100%], will be used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ilam Emam Khomeini hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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6939177143
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Jamil.sadeghifar@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
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Atiyeh zolfaghari
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document

Individual Participant Data (IPD) from a randomized clinical trial comparing TIVA with propofol versus isoflurane on emergence delirium in abdominal surgery

When the data will become available and for how long

Data will be available after publication of the main results (expected 12 months after study completion) and will remain accessible for 5 years.

To whom data/document is available

Qualified researchers from academic institutions with a valid research proposal and ethics approval, upon reasonable request to the corresponding author (Atieh Zolfaghari, zola69440@gmail.com)

Under which criteria data/document could be used

The de-identified IPD and supporting documents (protocol, SAP, data dictionary) may be used exclusively for: (1) secondary analyses related to postoperative cognitive outcomes, delirium, or anesthetic techniques; (2) systematic reviews and meta-analyses; (3) methodological validation or replication studies. Users must not use the data for commercial purposes, must maintain confidentiality, and must cite the original study in any resulting publications. Any secondary analysis must be approved by the corresponding author and the ethics committee of the user's institution.

From where data/document is obtainable

Requests for data and supporting documents should be directed to the corresponding author: Atieh Zolfaghari, Department of Anesthesiology, Ilam University of Medical Sciences, Ilam, Iran. Email: zola69440@gmail.com. Postal address: Ilam University of Medical Sciences, Ilam, Iran. Telephone: +98-9964871066.

What processes are involved for a request to access data/document

The request process includes the following steps: (1) The applicant submits a formal request via email to the corresponding author, including a brief research proposal, intended analysis plan, and ethics approval from their institution. (2) The request is reviewed by the research team for scientific validity and ethical compliance. (3) If approved, the applicant signs a data-sharing agreement ensuring confidentiality, non-commercial use, and proper citation. (4) The de-identified data and relevant documents are shared via a secure online repository (e.g., Zenodo or Figshare) with a password-protected link. The entire process is expected to take approximately 2-4 weeks.

Comments

This study is registered in the Iranian Registry of Clinical Trials (IRCT). The full protocol and SAP are available as supplementary materials in the main publication. Any publications using these data should cite the primary study and acknowledge the funding source (Ilam University of Medical Sciences).