Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Ratio of the Effects of Total Intravenous Anesthesia TIVA with Propofol versus Inhalation Anesthesia Isoflurane on the incidence of Myoclonic Movements Based on Gender Differences in Adults Undergoing Abdominal Surgery

Protocol summary

Study aim
Comparison of propofol TIVA versus isoflurane inhalation on myoclonic movements and hemodynamics in abdominal surgery considering gender

Design
Randomized double-blind parallel-group trial, 182 patients 1:1 with blocks of four. Anesthesiologist unblinded; patients, assessor, analyst blinded. Control: isoflurane

Settings and conduct
Imam Khomeini Hospital, Ilam, elective abdominal surgery, myoclonus recorded every 15 minutes by blinded observer

Participants/Inclusion and exclusion criteria
Inclusion: age 18-65, ASA I/II, elective abdominal surgery, no neurologic disease, no CNS drugs, no allergy, not pregnant. Exclusion: withdrawal, severe complications, new diagnosis, need for method change.

Intervention groups
Intervention: propofol 100-150 µg/kg/min IV plus fentanyl. Control: isoflurane 0.8-1.2 MAC. Induction identical

Main outcome variables
Incidence and severity of myoclonus using four-point scale (none, mild, moderate, severe)

General information

Reason for update

Acronym
PIMA

IRCT registration information
IRCT registration number: **IRCT20260803070523N1**
Registration date: **2026-10-28, 1405/08/06**
Registration timing: **registered_while_recruiting**
Last update: **2026-10-28, 1405/08/06**
Update count: **0**

Registration date
2026-10-28, 1405/08/06

Registrant information

Name
Fatemeh Rostami
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 83 4522 7035
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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
Ratio of the Effects of Total Intravenous Anesthesia TIVA with Propofol versus Inhalation Anesthesia Isoflurane on the incidence of Myoclonic Movements Based on Gender Differences in Adults Undergoing Abdominal Surgery

Public title
Comparison of Two Anesthesia Methods on Myoclonic

Movements in Abdominal Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing abdominal surgery under general anesthesia Age between 18 and 65 years ASA physical status class I or II

Exclusion criteria:

History of neurological or neuromuscular disorders (epilepsy, myoclonus, myasthenia gravis) Use of medications affecting the central nervous system in the past week (benzodiazepines, antidepressants, antipsychotics) Known hypersensitivity to propofol or isoflurane Cognitive or psychiatric disorders that may interfere with proper evaluation or cooperation with the treatment team Pregnancy or breastfeeding

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: **182**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent, eligible patients will be randomly allocated into two equal groups (91 patients per group) using block randomization with block sizes of 4. The allocation ratio is 1:1. Randomization codes will be generated by the principal investigator and sealed in opaque, unlabeled envelopes. The envelopes will be opened immediately before the induction of anesthesia by the attending anesthesiologist who is not involved in the randomization process. The principal investigator is aware of the allocation process but is not involved in outcome assessment or data collection. The unit of randomization is the individual patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind randomized clinical trial, three main groups are masked to the treatment allocation: 1. Participants (Patients): Patients receive comprehensive information about the study objectives, procedures, and potential complications one day before surgery, but they remain unaware of the type of anesthesia maintenance method assigned to them (TIVA with propofol versus isoflurane inhalation anesthesia). 2. Clinical Caregivers (except the attending anesthesiologist): Operating room nurses, anesthesia assistants, and recovery room personnel are unaware of the intervention type. Anesthesia drugs are prepared in identical containers without identifying labels and are provided to the anesthesiologist. Only the attending anesthesiologist who administers the drugs is aware of the intervention but is not involved in outcome assessment. 3. Outcome Assessor: A trained research observer who is responsible for evaluating and recording myoclonic movements and hemodynamic parameters during surgery and in the recovery room is completely blinded to the group allocation and has no knowledge of the anesthesia method received by each patient. This assessor is independent of the clinical care team. Other groups: · Attending Anesthesiologist: Is aware of the intervention type as they must administer the assigned drug (propofol or isoflurane), but they are not involved in outcome assessment. · Principal Investigator: Has access to the randomization codes and group assignments but is not involved in drug administration or outcome evaluation. · Data Analyst: Analyzes data based on group allocation and is therefore not blinded.

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

Eslamabad-e Gharb Opposite the Governor's Office, Rajaei St., No. 62

City

Islam Abad Gharb

Province

Kermanshah

Postal code

۶۷۶۱۸۳۳۴۳۹

Approval date

2026-06-23, 1405/04/02

Ethics committee reference number

IR.MEDILAM.REC.1405.078

Health conditions studied

1

Description of health condition studied

Myoclonus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Incidence of any sudden, brief, involuntary, and jerky muscle contractions (myoclonic movements), recorded as a binary event (Yes/No).
Timepoint
Continuously from the induction of anesthesia until the end of surgery (every 15 minutes by a research observer in the operating room).
Method of measurement
Direct observation and recording of movements by a trained research observer who is blinded to the patient's group allocation.

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
Control group: 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 us
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ilam Imam Khomeini Hospital
Full name of responsible person
Fatemeh Rostami
Street address
Eslamabad-e Gharb, Opposite the Governor's Office, Shahid Rajaei St., No. 62,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
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Ilam
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Phone
+98 912 447 4770
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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
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
Ilam University of Medical Sciences
Full name of responsible person
Fatemeh Rostami
Position
Anesthesia Stu
Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

No. 62, Shahid Rajaei Street, Opposite the Governor's Office,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Fatemeh Rostami

Position

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Latest degree

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Person responsible for updating data

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Position

Anesthesia Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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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

IPD (Individual Participant Data): Anonymized individual participant data including demographic information, hemodynamic parameters, incidence and severity of myoclonic movements, total anesthetic drug dosage, length of stay in recovery, and Aldrete scores. All data will be shared after removing identifiable information (name, national ID, medical record number). Study Protocol: Full study protocol including objectives, methods, inclusion and exclusion criteria, interventions, outcomes, statistical analysis plan, and ethical considerations. Statistical Analysis Plan (SAP): Detailed statistical methods including tests to be used, management of missing data, adjustment methods for confounding variables, and Intention-to-Treat approach. Informed Consent Form: Written informed consent form approved by the ethics committee, containing complete explanations for patients regarding objectives, methods, potential complications, and participants' rights.

When the data will become available and for how long

Access to data and documents will be available starting 12 months after publication of the main study results and will continue for 5 years.

To whom data/document is available

Qualified researchers who provide a reasonable and well-justified request for data access. Access will be granted upon approval by the principal research team and with full compliance with patient data confidentiality requirements.

Under which criteria data/document could be used

Data may be used solely for research and scientific purposes such as meta-analysis, secondary analyses, or replication of results. Any use of the data must be accompanied by proper citation of the original study. Commercial use or redistribution of data without

permission from the research team is prohibited. All users are required to maintain the confidentiality of participant information.

From where data/document is obtainable

For access to study data and documents, please contact the Principal Investigator, Ms. Fatemeh Rostami, via the following email: Email: fa.rostamiii1382@gmail.com Mobile: +98 9960758982 If no response is received, you may also contact the Vice-Chancellery for Research and Technology, Ilam University of Medical Sciences: Address: Vice-Chancellery for Research and Technology, Ilam University of Medical Sciences, Farhang Street, Ilam, Iran

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

Applicants must first submit a written request along with a detailed description of the purpose of using the data and documents to the principal investigator's email. The request will be reviewed by the main research team. Upon approval, the applicant will be required to sign a confidentiality agreement and a non-commercial use commitment. After these steps, anonymized data will be provided in Excel or SPSS format. The entire process will be completed within a maximum of 2 to 4 weeks after submission of the request.

Comments