Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of combined low-dose Epinephrine and Propofol infusion on Hemodynamic statues and Anesthesia-related complication: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of simultaneous injection of propofol and low-dose epinephrine on hemodynamic status and anesthesia-related complications and the amount of additional medication needed to control hemodynamic status and anesthesia complications

Design

Phase 3 randomized, double-blind, parallel-group control clinical trial on 60 patients using Random allocation software for randomization

Settings and conduct

In this double-blind trial, after obtaining consent, an independent person randomly assigns participants to either an epinephrine group (standard anesthesia + epinephrine) or a control group (standard anesthesia + placebo). Only the research assistant knows the allocation; the principal investigator and participants are blinded. Hemodynamic parameters and postoperative complications are recorded and compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18–45 years ASA class I or II (without significant cardiovascular disease) Provision of written informed consent exlusion: Individuals with coagulopathy, cardiac disease, hypertension, cerebrovascular disease, peripheral vascular disease, or drug allergy Patient unwillingness Detection of severe hemodynamic instability Unexpected findings on baseline laboratory tests Inability to ensure standard conditions for baseline measurements Consumption of alcohol or caffeine

Intervention groups

General anesthesia with epinephrine: After induction of anesthesia by the anesthesiologist, a 1:10,000 dilution of epinephrine at a dose of 50 micrograms will be injected by the surgeon.

Main outcome variables

Systolic blood pressure; Diastolic blood pressure; Mean arterial pressure; Pulse rate; Respiratory rate; Peripheral oxygen saturation; Adverse events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251005067513N1**
Registration date: **2026-05-16, 1405/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-16, 1405/02/26**
Update count: **0**

Registration date

2026-05-16, 1405/02/26

Registrant information

Name

Mohammad javad Torkan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2027-05-22, 1406/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combined low-dose Epinephrine and Propofol infusion on Hemodynamic statues and Anesthesia-related complication: A Randomized Clinical Trial

Public title
The effect of simultaneous injection of propofol and epinephrine in anesthesia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Age 18 to 45 years 2. ASA class I and II (except for hypertension and cardiac disease) 3. Written consent to participate in the study
Exclusion criteria:
People with coagulation disorders, heart disease, hypertension, cerebrovascular disease, peripheral vascular disease, or drug allergies Patient unwillingness to continue participation in the study or failure to sign the informed consent form. Alcohol and caffeine consumption Detection of any severe hemodynamic instability or unexpected need for emergency intervention during initial monitoring/assessment. Unexpected findings on baseline laboratory tests (if performed) that constitute a contraindication to the intervention. Inability to ensure standard conditions for baseline measurements (e.g., severe uncooperativeness).
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining the researcher's consent, subjects will be randomly assigned to one of the two intervention and control groups using the Random Allocation software using permutation block allocation. For this purpose, 10 blocks of size 6 will be prepared and provided to an outsider to assign patients to the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
An independent statistician generated the randomized sequence using variable blocks and placed it in opaque, sequentially numbered envelopes. A research assistant (who had no role in patient care) prepared identical syringes containing either 50 µg of epinephrine or normal saline, labeled only with the patient's code. Patients, the anesthesiologist, the surgeon, operating room personnel, the outcome assessor, and the data analyst were all blinded to group allocation until the analysis was completed. The study drug was administered by the research assistant through a separate port so that the treatment team could not see the syringe contents. No blinding violation occurred. All patients provided written informed consent to participate in the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Kashani Street, Shahrekord town
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
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Approval date
2025-09-28, 1404/07/06
Ethics committee reference number
IR.SKUMS.REC.1404.100

Health conditions studied

1

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

Primary outcomes

1

Description
Mean heart rate (beats per minute) at four time points: before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3).

Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3)
Method of measurement
Same pulse oximetry

2

Description
Determining and comparing the mean blood pressure score of patients undergoing surgery under general anesthesia with propofol before, immediately, and after the intervention in the two intervention and control groups, within and between groups.
Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), end of surgery (T3)
Method of measurement
Cuffs of the same size arm in the same place for the same people

3

Description
Mean arterial oxygen saturation percentage (SpO_2) at four time points: before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3).
Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), end of surgery (T3)
Method of measurement
Same Pulse oximetry

4

Description
Mean respiratory rate (breaths per minute) at four time points: before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3).
Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), end of surgery (T3)
Method of measurement
Counting the number of breaths per minute

5

Description
Occurrence of any electrocardiogram rhythm or morphology changes including ventricular tachycardia, bradycardia requiring treatment, ventricular or atrial extrasystoles, and ST segment changes during anesthesia until the end of recovery.
Timepoint
Continuously from before induction (T0) until the end of recovery (up to 2 hours after surgery), recording any clinically significant change
Method of measurement
ECG

6

Description
Frequency of the following adverse events within 30 minutes after arrival in the post-anesthesia care unit: nausea, vomiting, post-anesthetic shivering, arrhythmia diagnosed by electrocardiogram, and severe pain (visual analogue scale score ≥ 7).
Timepoint
Continuously during the first 30 minutes after transfer to the recovery room; pain assessment at arrival and at 30 minutes
Method of measurement
Follow up

7

Description
Mean diastolic blood pressure (mmHg) at four time points: before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3).
Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), end of surgery (T3)
Method of measurement
Cuffs of the same size arm in the same place for the same people

8

Description
Mean arterial pressure (mmHg) at four time points: before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), and at the end of surgery (T3).
Timepoint
Before induction (T0), one minute post-induction (T1), three minutes post-induction (T2), end of surgery (T3)
Method of measurement
Cuffs of the same size arm in the same place for the same people (1/3 SBP* 2/3 DBP)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: General anesthesia with epinephrine: After induction of anesthesia by the anesthesiologist, a 1:10,000 dilution of epinephrine at a dose of 50 micrograms will be injected by the surgeon. Epinephrine will be injected after all anesthesia judges have been injected during induction of anesthesia.
Category
Treatment - Drugs

2

Description
Control group: Participants in this group will receive an equal volume (0.5 mL) of 0.9% normal saline (0.9% sodium chloride solution) as placebo. This placebo will be prepared by the research assistant in an identical syringe with exactly the same appearance as the epinephrine syringe (colorless and clear solution). It will be administered immediately after completion of anesthesia induction (midazolam, fentanyl, propofol, and cisatracurium) via a separate intravenous port as a rapid intravenous bolus over 5–10 seconds. The timing of injection, injection site (the arm opposite to the anesthesia drug infusion line), and injection speed are identical in both groups. Participants, the treatment team (anesthesiologist, surgeon, nurse), and the outcome assessor are blinded to the type of injected solution. No additional additives or preservatives are present in the placebo syringe.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital

Full name of responsible person
Alireza Babaeizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Akbar Soleimani

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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Mohammad javad Torkan

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available