

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effects of etomidate, propofol and etomidate combined with propofol injections on hemodynamic changes in high blood pressure patients who are candidates for general anesthesia

Protocol summary

Study aim

Investigating the effects of etomidate, propofol and etomidate combined with propofol injections on hemodynamic changes in high blood pressure patients who are candidates for general anesthesia

Design

Clinical trial with parallel groups, double-blind, randomized, phase 3, on 150 patients. Excel software will be used for randomization.

Settings and conduct

This study aims to investigate the effects of etomidate, propofol and etomidate combined with propofol on hemodynamic changes in high blood pressure patients candidates for general anesthesia in abdominal surgeries in Fatemi Ardabil Hospital. The first group will receive propofol, the second group will receive etomidate, and the third group will receive etomidate and propofol. Blood pressure and heart rate will be evaluated in these patients. Patients and those evaluating the outcome will not know about the grouping done and the study will be double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with blood pressure between 140/80 and 170/90 are candidates for abdominal surgery. Exclusion criteria: Patients with hemodynamic disorder who need therapeutic fluid and vasopressor.

Intervention groups

The intervention group will include patients with high blood pressure who are candidates for general anesthesia in abdominal surgeries, the first group will receive propofol (1.5-2 mg/kg), the second group will receive etomidate (0.3 mg/kg), and the third group will receive etomidate and propofol (propofol mg 1/kg and etomidate 0.15 mg/kg) and their blood pressure and heart rate will be checked after induction.

Main outcome variables

Blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231222060494N1**

Registration date: **2024-01-07, 1402/10/17**

Registration timing: **prospective**

Last update: **2024-01-07, 1402/10/17**

Update count: **0**

Registration date

2024-01-07, 1402/10/17

Registrant information

Name

Somayye Najafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 7343

Email address

drsomayye@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of etomidate, propofol and etomidate combined with propofol injections on hemodynamic changes in high blood pressure patients who are candidates for general anesthesia

Public title

Effects of etomidate, propofol and etomidate combined with propofol on hemodynamic changes in high blood pressure patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with blood pressure between 140/80 and 170/90 are candidates for abdominal surgery

Exclusion criteria:

Patients with hemodynamic disorder who need therapeutic fluid and vasopressor.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into three groups receiving propofol, etomidate and etomidate and propofol. Randomization in this study is done by simple randomization method using RAND function of Excel software. First, 150 random numbers are created in one column using the Rand function. Then, in the second column of the numbers from 1 to 150, a new random code is inserted in front of each column. Finally, in the third column, 50 lines with code A, 50 lines with code B, and 50 lines with code C are filled. After arranging the size of the numbers in the first column using the software, keeping their connection to the numbers in the second and third columns, the random sequence in the third column is ready. The numbers in the second column, each assigned to one of the three groups based on the corresponding line in the third column, can be used as the row code used in hiding.

Blinding (investigator's opinion)

Double blinded

Blinding description

In patients of the intervention groups, the form of drugs will be the same. Patients and doctors who evaluate the outcome will be unaware of the type of drug received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Ave, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2023-12-04, 1402/09/13

Ethics committee reference number

IR.ARUMS.REC.1402.279

Health conditions studied

1

Description of health condition studied

Hemodynamic status

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

The first, fifth and tenth minutes after induction

Method of measurement

Vital signs monitoring device

Secondary outcomes

1

Description

Pulse rate

Timepoint

The first, fifth and tenth minutes after induction

Method of measurement

Vital signs monitoring device

Intervention groups

1

Description

Intervention group: The group receiving propofol 1.5-2 mg/kg (Tehran shimi Co)

Category

Treatment - Drugs

2

Description

Intervention group: The group receiving etomidate 0.3 mg/kg (Aboreihan Co)

Category

Treatment - Drugs

3

Description

Intervention group: The group receiving etomidate and propofol (propofol 1 mg/kg and etomidate 0.15 mg/kg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital in Ardabil

Full name of responsible person

Somayye Najafpour

Street address

Fatemi hospital, Imam Khomeini street, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Email

fatemi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Farhad Pourfarzi

Street address

Vice chancellor for research, Ardabil University of Medical Sciences, Daneshgah Ave, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3353 4757

Email

research@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Somayye Najafpour

Position

Resident of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Fatemi hospital, Imam Khomeini street, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Email

drsomayye@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Somayye Najafpour

Position

Resident of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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City

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Phone

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Email

drsomayye@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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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