

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the effectiveness of low-dose Ephedrine and Ketamine injections on rapid sequence intubation using Priming Dose of Cis-Atracurium in patients under general anesthesia

#### Protocol summary

##### Study aim

Comparison of the effect of Ephedrine and Ketamine injection on rapid chip piping with Priming dose method

##### Design

A clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 128 patients. A randomization table is used for randomization

##### Settings and conduct

This study is a double-blind randomized controlled clinical trial in which the target population will be candidates for elective surgery under general anesthesia in Al-Zahra Hospital in Isfahan. Patients are divided into 4 groups by simple random allocation. After being placed on the operating table and connected to the monitor, each group was injected with one of the drug interventions before the induction of anesthesia. The patient's vital signs and hemodynamic status are monitored and recorded before, during, and after surgery. The intervention groups are coded so the injector, clinical caregiver, surgeon, and patient are unaware of the injected intervention and are blind

##### Participants/Inclusion and exclusion criteria

All patients with general anesthesia candidates aged 18 to 65 years and with class I ASA and II can enter this study if they have no history of hypersensitivity, either moderate to severe.

##### Intervention groups

Intervention group E: 70 micrograms of Ephedrine per kilogram of body weight, intervention group K: 0.5 mg of Ketamine per kilogram of body weight, intervention group E + K: 70 micrograms of Ephedrine and 0.5 mg of Ketamine and group N: Normal saline is injected into patients before induction of anesthesia.

##### Main outcome variables

Mouth opening; Jaw condition; , The condition of the vocal cords; Diaphragm position

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160307026950N24**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

##### Registration date

2020-09-19, 1399/06/29

##### Registrant information

##### Name

Behzad Nazemroaya

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3212 3543

##### Email address

behzad\_nazem@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effectiveness of low-dose Ephedrine and Ketamine injections on rapid sequence intubation using Priming Dose of Cis-Atracurium in patients under general anesthesia

### Public title

Effect of Ephedrine and Ketamine on rapid sequence intubation using Priming Dose of Cis-Atracurium

### Purpose

Diagnostic

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients are candidates for elective surgery under general anesthesia Age 18 to 65 years ASA Class I and II Anesthesia Patient consent to study

#### Exclusion criteria:

History of moderate to severe allergy

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **128**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is done in a simple way so that the names of patients enter the randomization software (<https://random-allocation-software.software.informer.com/2.0/>) if they have the necessary conditions and according to the time of entry. software Randomly assign numbers to each patient, and based on these numbers, patients enter one of the intervention or control groups so that their number reaches the required number in each group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Four packs of drugs A, B, C, D are prepared, each of which contains coded syringes of one shape, and for each patient, a syringe is selected from the packs according to their selected group. And is injected into the patient, the prescriber (anesthesiologist), and the person who records the symptoms Also, patients are unaware of the prescribed drug and therefore both parties are blind.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezarjarib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2019-08-26, 1398/06/04

#### Ethics committee reference number

IR.MUI.MED.REC.1398.644

## Health conditions studied

### 1

#### Description of health condition studied

Rapid sequence intubation

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Reaction to laryngoscopy

#### Timepoint

60 seconds after Cis Atracurium injection

#### Method of measurement

Cooper Scoring Criterion

### 2

#### Description

Position of vocal cords

#### Timepoint

60 seconds after Cis Atracurium injection

#### Method of measurement

Cooper Scoring Criterion

### 3

#### Description

Diaphragm muscle movement

#### Timepoint

60 seconds after Cis Atracurium injection

#### Method of measurement

Cooper Scoring Criterion

## 4

### **Description**

Opening the patient's mouth

### **Timepoint**

60 seconds after Cis Atracurium injection

### **Method of measurement**

Cooper Scoring Criterion

## **Secondary outcomes**

### 1

#### **Description**

Heart rate

#### **Timepoint**

Before induction of anesthesia, after induction of anesthesia, and every 15 minutes until the end of anesthesia

#### **Method of measurement**

ECG monitoring

### 2

#### **Description**

Oxygen saturation

#### **Timepoint**

Before induction of anesthesia, after induction of anesthesia, and every 15 minutes until the end of anesthesia

#### **Method of measurement**

Pulse oximeter

### 3

#### **Description**

Blood Pressure

#### **Timepoint**

Before induction of anesthesia, after induction of anesthesia, and every 15 minutes until the end of anesthesia

#### **Method of measurement**

Non-invasive blood pressure measurement

### 4

#### **Description**

Drug side effects

#### **Timepoint**

From the end of anesthesia to the end of recovery

#### **Method of measurement**

Observe and ask the patient

### 5

#### **Description**

Recovery time

#### **Timepoint**

From the end of anesthesia to the exit of recovery

#### **Method of measurement**

Timer

## **Intervention groups**

### 1

#### **Description**

Intervention group E: each patient is injected with Ephedrine 70 Mgr/kg before induction.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: K: That each patient is injected with 0.5 mg/kg Ketamine before induction.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group E + K: each patient is injected with 70 micro grams of Ephedrine and 0.5 mg of Ketamine per kilogram of body weight before induction.

#### **Category**

Treatment - Drugs

### 4

#### **Description**

Control group N: Normal saline is injected into the patient before induction.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Isfahan Alzahra hospital

##### **Full name of responsible person**

Behzad Nazem Roaya

##### **Street address**

Soffeh Boulevard, Shahid Keshvari Highway

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3620 2020

##### **Email**

behzad\_nazem@med.mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

**Street address**

Esfahan University of Medical Sciences, Hezar Jarib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Pouyan Nadery Afshar

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Esfahan University of Medical Sciences, Hezar Jarib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8146713543

**Phone**

+98 31 3620 2020

**Email**

behzad\_nazem@med.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Behzad Nazem Roaya

**Position**

Professor assistant of Anesthesia and Intensive care intensive care

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Hezarjarib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8146713543

**Phone**

+98 31 3620 2020

**Email**

behzad\_nazem@med.mui.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Leyla Raffei

**Position**

Nurse Anesthesia

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Esfahan University of Medical Sciences, Hezar Jarib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8146713543

**Phone**

+98 31 3620 2020

**Email**

leylaraffei943@gmail.com

**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