

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Preventive effect of ephedrine to counteract hemodynamic changes following induction of anesthesia with propofol and remifentanil

#### Protocol summary

##### Summary

Background: Propofol is a short acting intravenous hypnotic drug used for induction and maintenance of general anesthesia and sedative purposes. One of the complications of induction of anesthesia by propofol is a substantial decrease in arterial blood pressure and heart rate which can be intensified by adding remifentanil, an ultra-short acting potent narcotic. In this study, two different doses of prophylactic ephedrine for coping with hemodynamic changes due to induction of anesthesia with propofol and remifentanil will be investigated. Materials and Methods: This study is a randomized clinical trial with a double-blind placebo-controlled design. 150 patients (ASA I and II) candidate for short-term minor elective surgery under general anesthesia are studied. Patients will be randomized to three groups: normal saline, ephedrine (0.07 mg/kg) and ephedrine (0.15 mg/kg). Anesthesia will be induced in all groups with propofol (2.5 mg/kg) and remifentanil (3 µg/kg). No neuromuscular blocking agent is used. The patients with history of hypertension, angina pectoris, heart failure, thyrotoxicosis, gastrointestinal reflux, and cerebrovascular disease, history of using anti-hypertensive or cardiac related drugs and hypersensitivity to eggs or soya bean will be excluded from the study. The patients' hemodynamic status would be assessed in 4 steps: immediately before, 2 minutes after induction of anesthesia, and 1 and 5 minutes after intubation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112061566N3**

Registration date: **2012-01-31, 1390/11/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-31, 1390/11/11

##### Registrant information

###### Name

Farid Zand

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4270

###### Email address

zandf@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-03-21, 1390/01/01

##### Expected recruitment end date

2012-01-21, 1390/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Preventive effect of ephedrine to counteract hemodynamic changes following induction of anesthesia with propofol and remifentanil

##### Public title

Effect of ephedrine to counteract hemodynamic changes following induction of anesthesia

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Exclusion criteria: 1) history of hypertension, angina pectoris, heart failure, thyrotoxicosis, gastrointestinal reflux, and cerebrovascular disease, 2) Use of muscle relaxants during operation, 3) history of using anti-hypertensive or cardiac related drugs, 4) hypersensitivity to eggs, 5) hypersensitivity to soya bean, 6) patient's dissatisfaction at any time. Inclusion criteria: 1) age range of 20-50 years, 2) ASA I & II, 3) weight of 60-80 kg, 4) candidate for short-term operations under general anesthesia.

### **Age**

From **20 years** old to **50 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **143**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

##### **Street address**

Zand Blvd.

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2011-03-05, 1389/12/14

#### **Ethics committee reference number**

CT-84-2050

## **Health conditions studied**

### 1

#### **Description of health condition studied**

hypotension and heart rate fluctuation resulting from anesthesia induction

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Hypotension resulting from anesthesia induction

#### **Timepoint**

Before intervention, 2 minutes after anesthesia induction, 1 and 5 minutes after tracheal intubation

#### **Method of measurement**

Operating room monitor

### 2

#### **Description**

Heart rate fluctuation resulting from anesthesia induction

#### **Timepoint**

Before intervention, 2 minutes after anesthesia induction, 1 and 5 minutes after tracheal intubation

#### **Method of measurement**

Operating room monitor

## **Secondary outcomes**

### 1

#### **Description**

Cardiac arrhythmia resulting from anesthesia induction

#### **Timepoint**

Continuous monitoring from the patients' entrance to the operating room until five minutes after tracheal intubation

#### **Method of measurement**

Operating room monitor

## **Intervention groups**

### 1

#### **Description**

Case group 1: Besides normal anesthesia induction drugs, ephedrine 0.07mg/kg was infused by a 2cc syringe

#### **Category**

Prevention

### 2

#### **Description**

Case group 2: Besides normal anesthesia induction drugs, ephedrine 0.15mg/kg was infused by a 2cc syringe

#### **Category**

Prevention

### 3

#### Description

Control group: Besides normal anesthesia induction drugs, distilled water was infused by a 2cc syringe as placebo

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shahid Chamran Hospital

###### Full name of responsible person

###### Street address

###### City

Shiraz

#### 2

##### Recruitment center

###### Name of recruitment center

Khalili Hospital

###### Full name of responsible person

###### Street address

###### City

Shiraz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Full name of responsible person

Mohammad Ali Sahmeddini

###### Street address

Zand st, Central building of the University

###### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shiraz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Ali Hosseinipour

##### Position

Anesthesiologist

##### Other areas of specialty/work

##### Street address

Zand St, Shahid Faghihi Hospital

##### City

Shiraz

##### Postal code

##### Phone

+98 71 1832 3519

##### Fax

##### Email

hoseinipur@sums.ac.ir; alihoseinpour@gmail.com

##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Farid Zand

##### Position

Anesthesiologist, Associate professor

##### Other areas of specialty/work

##### Street address

Zand St, Shahid Faghihi Hospital

##### City

Shiraz

##### Postal code

##### Phone

+98 71 1233 7636

##### Fax

##### Email

zandf@sums.ac.ir

##### Web page address

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Ali Hosseinipour

##### Position

Anesthesiologist

##### Other areas of specialty/work

##### Street address

##### City

Shiraz

##### Postal code

7185734587

##### Phone

+98 71 1832 3519

**Fax**

**Email**

alihoseinipour@gmail.com,hoseinipur@sums.ac.ir

**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*