

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### comparison of effects of ephedrine, lidocaine and ketamine with placebo on injection pain and hypotension & bradycardia due to propofol injection in patient under general anesthesia

#### Protocol summary

##### Summary

The purpose of this study is selection of the best drug among three available drugs: ephedrine, lidocaine and ketamine with a low dose to reduce injection pain and hypotension and bradycardia due to propofol injection. This randomized double-blinded placebo-controlled clinical trial study perform on 140 patients 20-40 years in ASA class I, who are candidate for elective surgery and anesthesia induction with propofol and the first experience of anesthesia. Patients randomly allocate to receive ephedrine 0.1mg/kg (Group E, n = 35) or lidocaine 2% (group L, n=35) or ketamine 0.1mg/kg (group K, n=35) or normal saline (group N, n=35) in volumes of 2cc, intravenously 30 second before propofol injection. During slow injection of propofol, pain and its severity is assessed with 4 points scale (0=no pain , 1=mild pain with frown, 2=moderate pain with frown and whine , 3=sever pain with withdrawal movement of hand and squeal ). Then 1.5- 2 cc fentanyl and 0.5 mg/kg atracurium is injected and after 3 min ventilation, trachea is intubated. systolic, diastolic and mean blood pressure and heart rate are measured and recorded before induction, just before intubation and after tracheal intubation. finally we analyze the collected data with using statistical software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102055764N1**  
Registration date: **2011-04-12, 1390/01/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-12, 1390/01/23

##### Registrant information

###### Name

Vida Ayatollahi

###### Name of organization / entity

Shahid Sadoughi University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1821 5730

###### Email address

ayatt.vida@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2009-12-22, 1388/10/01

##### Expected recruitment end date

2011-01-20, 1389/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of effects of ephedrine, lidocaine and ketamine with placebo on injection pain and hypotension & bradycardia due to propofol injection in patient under general anesthesia

##### Public title

Which drug is better for reducing injection pain and hypotension & bradycardia due to propofol injection

## Purpose

Prevention

## Inclusion/Exclusion criteria

inclusion criteria: ; All of patients in ASA class I, who are candidated for elective surgery and anesthesia with propofol and this anesthesia is the first experience for them; exclusion criteria: ;Any patients that has unpredictable complications during information recording to (such as bronchospasms , ....) pain at the Injection site before or during the study drugs injection (before injection of propofol) Previous sensitivity to study drugs anxiety and lack of cooperation;

## Age

From **20 years** old to **40 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **140**

## 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

Ethics committee of Medical Sciences and Health Services Shaid Sadoughi university

##### Street address

Central Organization of Medical Sciences and Health Services Shahid Sadoughi, Dr Bahonar Square

##### City

Yazd

##### Postal code

8916978477

#### Approval date

2009-06-07, 1388/03/17

#### Ethics committee reference number

17/1/22456/پ

## Health conditions studied

### 1

#### Description of health condition studied

propofol injection pain

#### ICD-10 code

y48.2

#### ICD-10 code description

Drugs, medicaments and biological substances causing adverse effects in therapeutic use

## Primary outcomes

### 1

#### Description

blood pressure

#### Timepoint

before starting. after injection and before tracheal int. after tracheal int

#### Method of measurement

mmHg by noninvasive automatic device

### 2

#### Description

propofol injection pain

#### Timepoint

during injection

#### Method of measurement

4 point visual

## Secondary outcomes

### 1

#### Description

heart rate

#### Timepoint

before starting. after injection and before tracheal int. after tracheal int

#### Method of measurement

bit/min by EKG and pulseoximetry

## Intervention groups

### 1

#### Description

efedrine- 0.1mg/kg- 2cc- iv-before propofol injection

#### Category

Prevention

### 2

#### Description

lidocaine 2%- 2cc- iv- before propofol injection

#### Category

Prevention

### 3

#### Description

ketamine- 0.1mg/kg- 2cc- iv- before propofol injection

#### Category

Prevention

#### 4

#### Description

normal saline- placebo- 2cc- iv- before propofol injection

#### Category

Placebo

### Recruitment centers

#### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi Hospital

##### Full name of responsible person

Dr Vida Ayatollahi, Anesthesiologist, Assistant professor

##### Street address

Ebnesina Str, Shahid Ghandi Aven, Shahid Sadoughi Hospital

##### City

Yazd

### Sponsors / Funding sources

#### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, .... University of shahid sadoughi medical university

##### Full name of responsible person

Dr Hassan Mozaffari

##### Street address

Medical University, Bahonar Square

##### City

Yazd

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, .... University of shahid sadoughi medical university

#### 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

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Sadoughi Medical University

##### Full name of responsible person

Dr Vida Ayatollahi

##### Position

Anesthesiologist

##### Other areas of specialty/work

##### Street address

Shahid Sadoughi Hospital, Safaiye, Yazd

##### City

Yazd

##### Postal code

##### Phone

+98 35 1822 4001

##### Fax

##### Email

ayatt.vida@ssu.ac.ir; ayati.vida@yahoo.com

##### Web page address

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Shahid Sadoughi University

##### Full name of responsible person

Dr Vida Ayatollahi

##### Position

Anesthesiologist, Member of group, Assistant professor

##### Other areas of specialty/work

##### Street address

Shahid Sadoughi Hospital

##### City

Yazd

##### Postal code

##### Phone

+98 35 1821 5730

##### Fax

##### Email

ayatt.vida@ssu.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*