

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography

#### Protocol summary

##### Summary

The purpose of this study is Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography. Patients aged 2 to 8 years, ASA I, II without metabolic, kidney and liver disease will be studied. 60patient refferd to Sina Hospital Tehran divided into 2 groups. in first group, induction of anesthesia will performed with ketamine and will maintained with sevoflurane and the Laryngeal mask airway. In the second group, induction and maintaine of anesthesia will performed with mixed propofol / ketamine and Laryngeal mask airway. in each group, heart rate, respiratory rate and arterial blood pressure will be checked and The 2 groups will be compared with each other.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015013012642N12**

Registration date: **2015-02-27, 1393/12/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-02-27, 1393/12/08

##### Registrant information

##### Name

Majid Golestani Eraghi

##### Name of organization / entity

Shahid Beheshti University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3336 0547

##### Email address

dr.golestani@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology of Tehran University of Medical Sciences

##### Expected recruitment start date

2015-03-01, 1393/12/10

##### Expected recruitment end date

2015-05-22, 1394/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography

##### Public title

The effect of anesthetic drugs on blood pressure and heart rate changes in patients with diagnostic angiography

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: ASA I,II, Children 2 to 8 years, Written consent from the parent exclusion criteria: patients with pulmonary, hepatic, renal and metabolic disease, Patients with a prior history of cardiac and thoracic surgery, Patients who need more airway support and

pulmonary care

### Age

From **2 years** old to **8 years** old

### Gender

Both

### Phase

1-2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

##### Street address

Ghods Ave, Keshavarz Boulevard

##### City

Tehran

##### Postal code

#### Approval date

2013-12-17, 1392/09/26

#### Ethics committee reference number

2172

## Health conditions studied

### 1

#### Description of health condition studied

Effects of anesthetic drugs in diagnostic angiography

#### ICD-10 code

T88.7

#### ICD-10 code description

Unspecified adverse effect of drug or medicament

## Primary outcomes

### 1

#### Description

Arterial oxygen pressure

#### Timepoint

Before and after induction of anesthesia

#### Method of measurement

arterial blood gaz analyzer device in mmHg

### 2

#### Description

Blood Pressure

#### Timepoint

Before and after induction of anesthesia

#### Method of measurement

Non-invasive barometer in mm Hg

## Secondary outcomes

### 1

#### Description

Arterial pressure of carbon dioxide

#### Timepoint

Before and after induction of anesthesia.

#### Method of measurement

By the analyzer device in mmHg

### 2

#### Description

arterial pulmonary blood pressure

#### Timepoint

Before and after induction of anesthesia.

#### Method of measurement

by angiography in mmHg

## Intervention groups

### 1

#### Description

in The first group, induction of anesthesia with intravenous injection ketamine with dose of one mg per killogeram and receive sevoflurane will started. After 3 minutes, Laryngeal mask airway will be inserted

#### Category

Prevention

### 2

#### Description

In the second group solution containing of 80 mg per liter ketamine / propofol and 0.1 mg per killogeram of the prepared solution was administered for induction of anesthesia then Anesthesia will performe with infusion of 0.01 mg per killogeram per minute of solution.Laryngeal mask will be inserted after 3 minutes

#### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Children Medical Center Hospital

**Full name of responsible person**

Majid Golestani Eraghi

**Street address**

Doctor Mohamed Gharib St, Keshavarz Boulevard

**City**

Tehran

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research and Technology of  
Tehran University of Medical Sciences

**Full name of responsible person**

Masood Yoonesian

**Street address**

Central Organization of Tehran University of Medical  
Sciences, Ghods Ave, Keshavarz Boulevard

**City**

Tehran

**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 and Technology of Tehran  
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**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Department of Anesthesiology, Tehran University of

Medical Sciences

**Full name of responsible person**

Behrang Nooralishahi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**

Keshavarz Boulevard, Doctor Mohamed Gharib St.

**City**

Tehran

**Postal code****Phone**

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**Fax****Email**

b-nooralishahi@sina.tums.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Department of Anesthesiology, Shahid Beheshti  
University of Medical Sciences

**Full name of responsible person**

Majid Golestani Eraghi

**Position**

Fellowship specialty anesthesia and intensive care

**Other areas of specialty/work****Street address**

Masih Daneshvari Hospital, Darabad Ave

**City**

Tehran

**Postal code****Phone**

+98 21 2712 2525

**Fax****Email**

dr.golestani@sbmu.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*