

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comparison of blood pressure control in two general anesthetics technique of isoflurane and propofol in two anti hypertensive nitroglycerine-Labetalol or remifentanil in functional sinus endoscopic surgery

#### Protocol summary

##### Summary

**Aims:** Comparison of blood pressure control in two general anesthetics technique of isoflurane and propofol in two anti hypertensive nitroglycerine-Labetalol or remifentanil in functional sinus endoscopic surgery.

**Design:** random, one-sided, single-centered, stage two clinical trials. **How to do:** Patients undergoing functional autonomic sinus endoscopy, which are indicative of controlled hypotension, are administered in both groups by anesthetics of inhaled isoflurane and venous propofol. Patients in each group are divided into two groups of patients, each with hyperthyroidism with either remifentanil or nitroglycerine-Labetalol. The main criteria for inclusion the study include patients undergoing functional sinus endoscopy, which should have a systolic blood pressure of more than 100 and a mean arterial pressure above 55. Main exclusion criteria include: patients with a history of blood pressure; antihypertensive drugs; addicted patients; use of nerve drugs; patients with coagulation disorder and anticoagulants. **Interventions:** Patients undergoing functional functional sinus endoscopy, which are indicative of hypotension, are administered to both groups of patients with inhaled anesthetics of isoflurane and venipuncture of propofol. Patients in each group are divided into two groups of patients, each with hyperthyroidism with either remifentanil or nitroglycerine-Labetalol. Main outcome variables: Blood pressure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017102715108N3**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-19, 1396/08/28

##### Registrant information

###### Name

Reza Safaeian

###### Name of organization / entity

Iran University of medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4464 0531

###### Email address

rezasafaa@hotmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-01-21, 1396/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of blood pressure control in two general

anesthetics technique of isoflurane and propofol in two anti hypertensive nitroglycerine-Labetalol or remifentanil in functional sinus endoscopic surgery

#### Public title

Blood pressure control in both intravenous and inhalation anesthetics in sinus surgery

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing functional sinus endoscopic surgery that should have a systolic blood pressure of more than 100 and an arterial hypertension above 55. Exclusion criteria: Patients with history of hypertension; antihypertensive drugs; addicted patients; use of neurological drugs; patients with coagulation disorder and anticoagulants.

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **84**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Patients are selected using randomized block method.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

##### City

Tehran

##### Postal code

#### Approval date

2016-09-05, 1395/06/15

#### Ethics committee reference number

IR.IUMS.REC 1395.9311174004

## Health conditions studied

### 1

#### Description of health condition studied

Blood pressure

#### ICD-10 code

R03.0

#### ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

## Primary outcomes

### 1

#### Description

Amount of blood pressure

#### Timepoint

At the entrance to the operating room, after the induction, 15, 30, 45, 60, 75, 90, and 105 minutes during surgery

#### Method of measurement

In mmHg using a mercury barometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients undergoing inhaled anesthetic of isoflurane and receive nitroglycerine-Labetalol.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Patients undergoing inhaled anesthetic of isoflurane and receive remifentanil.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group 3: Patients undergoing vein anesthetic of propofol and receive nitroglycerine-Labetalol.

#### Category

Treatment - Drugs

### 4

#### Description

Intervention group 4: Patients undergoing vein anesthetic of propofol and receive remifentanil.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Dr Reza Safaeian

**Street address**

Rasoul Akram Hospital, Satar Khan

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyed Kazem Malakouti

**Street address**

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

**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, Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

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## **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*