

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of hemodynamic changes due to intravenous or inhalational anesthetics for deep vitrectomy surgery

#### Protocol summary

##### Summary

Abstract: Material and methods: In a prospective and randomized clinical trial study eighty patients undergoing deep vitrectomy operations under general anesthesia were randomly allocated to receive either Isoflurane-Remifentanil (Group I) or total intravenous anesthesia with Propofol-remifentanil (TIVA) (group P) for maintenance of anesthesia. Anesthesia was induced in both groups with remifentanil 1 µg/kg, propofol 2 mg/kg and Atracorium 0.6 mg/kg. Maintenance was achieved with 1 MAC of Isoflurane, O2 50% in air at 4 L/min and infusion of remifentanil 0.1 µg/kg/min-1 in I group. But in the P group we used propofol up to 10mg/kg iv with remifentanyl 0.1 µg/kg iv for maintenance of anesthesia. Propofol infusion and desflurane were discontinued with the last surgical stitches, but remifentanil infusion continued in both groups until the eye was covered with shield. Hemodynamic variables were recorded during the operation and one hour postoperatively in different intervals. Keywords: vitrectomy, hemodynamics, intravenous, inhalation, anesthesia.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015010920588N2**

Registration date: **2015-10-06, 1394/07/14**

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

Last update:

Update count: **0**

##### Registration date

2015-10-06, 1394/07/14

##### Registrant information

##### Name

Darioush Moradi Farsani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 5555

##### Email address

dmoradi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-11-22, 1394/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of hemodynamic changes due to intravenous or inhalational anesthetics for deep vitrectomy surgery

##### Public title

Effect of inhalational and intravenous anesthetics on hemodynamic changes during surgery

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: The patients with American Society of anesthesiology class I and II aged 40-80 years who are candidate for deep Vitrectomy surgery. Exclusion criteria: Any event that changes surgery or anesthesia technique.

## Age

From **40 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization with random allocation table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan university of medicasciences

##### Street address

Research Deputy, Isfahan university of medicasciences, Hezarjrib Street, Isfahan, Iran

##### City

Isfahan

##### Postal code

#### Approval date

2014-12-11, 1393/09/20

#### Ethics committee reference number

13625 /8/3

## Health conditions studied

### 1

#### Description of health condition studied

vitrectomy

#### ICD-10 code

H30-H36

#### ICD-10 code description

detachment of retinal pigment epithelium

## Primary outcomes

### 1

#### Description

Systolic and dyastolic blood pressure

#### Timepoint

on arrival to recovery room, and then 30, 60, minutes and 2,4,8,16,24 hours after that.

#### Method of measurement

By blood pressure monitor in mmhg

## Secondary outcomes

### 1

#### Description

Nausea & vomiting

#### Timepoint

Before induction of anesthesia, 1 minute after induction,

#### Method of measurement

By pulse oxymetry; non invasive blood pressure monitoring;

## Intervention groups

### 1

#### Description

Intervention group 1 :we use propofol up to 10mg/kg iv with remifentanyl 0.1µgr/kg iv for maintenance of anesthesia. group. Intervention group 2 : Maintenance will achieve with 1 MAC of Isoflurane , O2 50% in air at 4 L.min and infusion of remifentanil 0.1 µg/kg/min

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2 : Maintenance will achieve with 1 MAC of Isoflurane , O2 50% in air at 4 L.min and infusion of remifentanil 0.1 µg/kg/min

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Feiz Hospital

##### Full name of responsible person

Dr Daryoush Moradi

##### Street address

Anesthesia department, Alzahra University Hospital, Soffeh Bulvar, Isfahan, Iran

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vce chancellor for research of Isfahan University of Medical Science

**Full name of responsible person**

dr Mehdi Nematbakhsh

**Street address**

Research daeputy, Isfahan university of medical science-Hezarjrib Street-Isfahan-Iranf

**City**

Isfahan

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

Yes

**Title of funding source**

Vce chancellor for research of Isfahan University of Medical Science

**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**

Isfahan University of Medical Science

**Full name of responsible person**

Daryoush Moradi

**Position**

Assistant Professor of Anesthesia and Critical care

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

Depatment of Anesthesia and critical care, Alzahra University Hospital, Hezarjrib street, Isfahan

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

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**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*