

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

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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

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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

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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

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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