Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of hemodynamic changes due to intravenous or inhalational anesthtics 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 µgr/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

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Name of organization / entity

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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 anesthtics 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/ه

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 oxymetery; 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
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Anesthesia department, Alzahra University Hospital, Soffeh Bulvar, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vce chancellor for research of Isfahan University of Medical Sciense
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 Sciense
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
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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