Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Adding Dexmedetomidine to Propofol versus Isoflurane on Hemodynamic Stability, Depth of Anesthesia, and postoperative Outcomes in Pars Plana Vitrectomy

Protocol summary

Study aim
To determine and compare the effect of adding dexmedetomidine to propofol or isoflurane on hemodynamic stability, depth of anesthesia, intraocular pressure (IOP), and postoperative complications in patients undergoing deep vitrectomy.

Design
In the present clinical trial study, 94 eligible deep vitrectomy candidates will be randomly enrolled in the study. At the time of entry into the study, their basic and clinical information will be assessed and recorded. Then, the patients will be divided into two groups of 47 patients using random allocation software.

Settings and conduct
This study is a triple-blind randomized clinical trial that will be conducted in 2026 at *Feiz Hospital*, Isfahan, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients between the ages of 18-70 years with ASA physical status class 1-3 2. Patients who are candidates for deep vitrectomy under general anesthesia. (The reason for choosing this type of surgery was explained in the section on necessity of performance) Exclusion criteria: 1- Patients with ASA physical status class 4 and above 2- Known allergy or sensitivity to the drugs used in the study (dexmedetomidine, propofol, isoflurane, atracurium, fentanyl, etc.)

Intervention groups
All patients will undergo general anesthesia and, before the start of surgery, will receive the same standard anesthesia induction protocol. In **Group 1**, anesthesia will be maintained with a continuous propofol infusion at a rate of **4–12 mg/kg/h**. In **Group 2**, following induction of anesthesia, anesthesia will be maintained with **1–2% isoflurane**, with the concentration adjusted according to the depth of anesthesia. The target **minimum alveolar concentration (MAC)** of isoflurane will be maintained between **0.8 and 1.2**.

Main outcome variables
SBP ,DBP,MAP,HR,RR,SPO2,Pain,Intraocular Pressure,Depth of anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201116049410N2**
Registration date: **2026-07-02, 1405/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-02, 1405/04/11**
Update count: **0**

Registration date
2026-07-02, 1405/04/11

Registrant information

Name
SeyedTaghi Hashemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3233 0066

Email address
st_hashemi@med.mui.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Adding Dexmedetomidine to Propofol versus Isoflurane on Hemodynamic Stability, Depth of Anesthesia, and postoperative Outcomes in Pars Plana Vitrectomy

Public title
Comparing the effect of adding dexmedetomidine to propofol or isoflurane in deep vitrectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between the ages of 18-70 years with ASA physical status class 1-3 patients who are candidates for deep vitrectomy under general anesthesia
Exclusion criteria:
Patients with ASA physical status class 4 and above Known allergy or sensitivity to the drugs used in the study (dexmedetomidine, propofol, isoflurane, atracurium, fentanyl, etc.) Impaired ocular function that is independent of underlying ocular disease and affects intraocular pressure History of recent eye surgery (less than 3 months ago) in the same eye Having neurological or mental illnesses that interfere with cooperation with the treatment team Patients with mental or physical disabilities that prevent them from understanding the study steps or participating effectively. Having an addiction to opioid products Pregnancy or breastfeeding Emergency deep vitrectomy surgeries
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, patients will be randomly assigned to the intervention groups. Due to the difference in the nature of the drugs used (propofol infusion versus isoflurane inhalation anesthesia), the anesthesiologist responsible for implementing the intervention will be aware of the type of treatment assigned and blinding is not possible.However, patients will not be aware of the type of maintenance anesthetic regimen they will receive and will be blinded to the assigned group. Also, the assessor of postoperative outcomes (including assessment of pain, nausea and vomiting, shivering, recovery score, and other variables of interest) and the person responsible for data collection will be unaware of the group allocation of patients. The data will also be provided to the statistical analyst with group codes (A and B), so that he will not be aware of the type of intervention in each group. Therefore, blinding will be performed at the level of the patient, the assessor of outcomes, and the statistical analyst, and only the anesthesiologist performing the intervention will be aware of the group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, School of Medicine, Isfahan University of Medical Sciences
Street address
No. 4 Building, Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street, Isfahan, Iran.
City
اصفهان
Province
Isfehan
Postal code
81746-73461
Approval date
2026-05-24, 1405/03/03
Ethics committee reference number
IR.MUI.MED.REC.1405.083

Health conditions studied

1

Description of health condition studied
Cardiovascular Complications, Hemodynamic Changes, and Depth of Anesthesia in Patients Undergoing Pars Plana Vitrectomy Under General Anesthesia
ICD-10 code
Z01.818
ICD-10 code description
Encounter for other preprocedural examination

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Every 15 minutes during surgery, immediately upon arrival in the post-anesthesia care unit (PACU), and every 15 minutes for one hour after admission to the PACU.
Method of measurement
Measured in **millimeters of mercury (mmHg)** using a **calibrated noninvasive blood pressure monitor**.

2

Description
Diastolic blood pressure
Timepoint
Every 15 minutes during surgery, immediately upon arrival in the post-anesthesia care unit (PACU), and every 15 minutes for one hour after admission to the PACU.
Method of measurement
Measured in **millimeters of mercury (mmHg)** using a **calibrated noninvasive blood pressure monitor**.

3

Description
Heart Rate
Timepoint
Every 15 minutes during surgery, immediately upon arrival in the post-anesthesia care unit (PACU), and every 15 minutes for one hour after admission to the PACU.
Method of measurement
Cardiac Monitoring

4

Description
Mean Arterial Pressure
Timepoint
Every 15 minutes during surgery, immediately upon arrival in the post-anesthesia care unit (PACU), and every 15 minutes for one hour after admission to the PACU.
Method of measurement
Measured in **millimeters of mercury (mmHg)** using a **calibrated noninvasive blood pressure monitor**.

5

Description
Depth of Anesthesia
Timepoint
هر 15 دقیقه حین عمل تا پایان عمل
Method of measurement
Bispectral Index (BIS) monitor.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ** Anesthesia will be maintained with a continuous **propofol infusion** at a rate of **4–12 mg/kg/h**, titrated to maintain a **Bispectral Index (BIS)** between **40 and 60**. In addition, **intravenous dexmedetomidine** will be administered as a loading dose of **1 µg/kg over 10 minutes** (**0.5 µg/kg** in patients at risk of bradycardia), followed by a continuous infusion at a rate of **0.2 µg/kg/h** until the end of surgery.
Category
Treatment - Drugs

2

Description
Intervention group: ** Following induction of anesthesia, anesthesia will be maintained with **1–2% isoflurane**, with the concentration titrated according to the depth of anesthesia to maintain a **Bispectral Index (BIS)** between **40 and 60**. The target **minimum alveolar concentration (MAC)** of isoflurane will be maintained between **0.8 and 1.2**. In addition, **intravenous dexmedetomidine** will be administered as a loading dose of **1 µg/kg over 10 minutes** (**0.5 µg/kg** in patients at risk of bradycardia), followed by a continuous infusion at a rate of **0.2 µg/kg/h** until the end of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Seyed Taghi Hashemi
Street address
Feiz Hospital , Qods Squre
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3445 2031
Email
Feiz@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Hezar Jerib Street , Azadi Squre
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
Research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Taghi Hashemi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology and Critical Care, Educational and Medical Center, Alzahra Hospital, Shohada-ye Soffeh Street, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 1992
Email
st_hashemi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Taghi Hashemi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology and Critical Care, Educational and Medical Center, Alzahra Hospital, Shohada-ye Soffeh Street, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 1992
Email
st_hashemi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Taghi Hashemi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology and Critical Care, Educational and Medical Center, Alzahra Hospital, Shohada-ye Soffeh Street, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 1992
Email
st_hashemi@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only data related to the effects of the study drugs on hemodynamic parameters and hemodynamic changes will be made publicly available. Access to the complete dataset containing potentially identifiable or sensitive information will be granted only upon reasonable request, following approval by the principal investigator and after verification of the requester's academic qualifications and the intended purpose of data use.

When the data will become available and for how long

One year after publication of the study results.

To whom data/document is available

Researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

The data will be made available to researchers affiliated with academic and scientific institutions for use in **comparative studies** and **systematic reviews**, upon reasonable request and in accordance with the study's data-sharing policy.

From where data/document is obtainable

Nikoo Heydari / 09138986159 / Heidarynikoo@gmail.com

What processes are involved for a request to access data/document

Individuals requesting access to the data should contact the principal investigator using the designated communication channels, according to the type of information requested. A response to the request will be provided within **one month**.

Comments