

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 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

Isfahan

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 Squire

City

Isfahan

Province

Isfahan

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 Squire

City

Isfahan

Province

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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