

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Conscious sedation/monitored anesthesia care versus general anesthesia in patients undergoing pars plana vitrectomy

#### Protocol summary

##### Study aim

Aim of this prospective observational study was the comparison of sedation /monitored anesthesia care versus general anesthesia in patients undergoing pars plana vitrectomy.

##### Design

In one group PPV will be done under general anesthesia and in the other group will be done under monitored anesthesia care(MAC) and conscious sedation.

##### Settings and conduct

If the patients could not tolerate IV sedation it can be converted to general anesthesia. Parameters were graded depending on the type of anesthesia: central eye position, anesthesia, akinesia of the eye and or body, soft tissue or orbital hemorrhage, and absence of vitreous bulge. Postoperatively quality of immobilization was assessed by a standardized questionnaire. spiteri et al. published and evaluated such a questionnaire in 2015. For the purpose of this study the questionnaire was slightly modified while leaving the core score system unchanged. This study will performed at Khalili hospital at Shiraz, Fars, Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are cooperative for conscious sedation and candidate for pars plana vitrectomy. Exclusion criteria: 1. patients who are uncooperative for conscious sedation 2. difficult surgeries

##### Intervention groups

40 patients who are candidate for 23 Gauge-pars plana vitrectomy(PPV) for vitreoretinal disorders will be included in this study and will be divided in to two groups.

##### Main outcome variables

Parameters were graded depending on the type of anesthesia: central eye position, anesthesia, akinesia of the eye and or body, soft tissue or orbital hemorrhage, and absence of vitreous bulge.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201120049450N3**

Registration date: **2024-03-04, 1402/12/14**

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

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

##### Registration date

2024-03-04, 1402/12/14

##### Registrant information

##### Name

Ehsan Namvar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 4088

##### Email address

namvar\_e@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-10, 1402/11/21

##### Expected recruitment end date

2024-03-18, 1402/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Conscious sedation/monitored anesthesia care versus general anesthesia in patients undergoing pars plana vitrectomy

#### Public title

Performing retinal surgery without general anesthesia and comparing its benefits compared to performing the same surgery with general anesthesia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

patients who are cooperative for conscious sedation and candidate for pars plana vitrectomy

##### Exclusion criteria:

patients who are uncooperative for conscious sedation, difficult surgeries

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Data analyser

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Since patients received general anesthesia, therefore all patients and data analyzers were blinded.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

###### Street address

shiraz khalili Hospital, Khalili street

###### City

Shiraz

###### Province

Fars

###### Postal code

7193636981

#### Approval date

2023-12-20, 1402/09/29

#### Ethics committee reference number

IR.SUMS.MED.REC.1402.455

### Health conditions studied

#### 1

##### Description of health condition studied

Retinal disorders

##### ICD-10 code

H35

##### ICD-10 code description

Other retinal disorders

### Primary outcomes

#### 1

##### Description

Parameters were graded depending on the type of anesthesia: central eye position, anesthesia, akinesia of the eye and or body, soft tissue or orbital hemorrhage, and absence of vitreous bulge.

##### Timepoint

After surgery

##### Method of measurement

The standardized questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: In intervention no.1 group (20 participants) PPV will be done under monitored anesthesia care(MAC) and conscious sedation.

##### Category

Treatment - Surgery

#### 2

##### Description

Intervention group: In intervention no.2 group (20 participants) PPV will be done under general anesthesia.

##### Category

Treatment - Surgery

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Khalili hospital

###### Full name of responsible person

Ehsan Namvar

**Street address**

Khalili hospital, Khalili, Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7193636981

**Phone**

+98 917 713 4116

**Email**

Namvar\_e@sums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ehsan Namvar

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**Province**

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**Phone**

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**Email**

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ehsan namvar

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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Shiraz University of Medical Sciences

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## 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**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Conscious sedation/monitored anesthesia care versus general anesthesia in patients undergoing pars plana vitrectomy The amount of pain Suitability of eye position for surgery eye immobility No bleeding Softness of the eyes immobility of the body Hemodynamic stability

**When the data will become available and for how long**

after publishing

**To whom data/document is available**

public

**Under which criteria data/document could be used**

all of data

**From where data/document is obtainable**

under the web

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

email to responsible person

**Comments**