

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

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Email

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

Shiraz University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Namvar

Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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