

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of fentanyl-etomidate, fentanyl-propofol and fentanyl-midazolam for sedation in phacoemulsification

#### Protocol summary

##### Study aim

Determination of the sedation effect of fentanyl-etomidate, fentanyl-propofol and fentanyl-midazolam on Phacoemulsification

##### Design

randomized double-blind Clinical trial based on random numbers

##### Settings and conduct

In this study, both the participants and the data collector were blind to the allocation of the participants into propofol, midazolam and etomidate groups. The study drugs were prepared in 4 syringes covered with aluminum foil, by an anesthesiologist who was not involved in data collection.<sup>1</sup>

##### Participants/Inclusion and exclusion criteria

Inclusion: Patients who are candidates for cataract surgery, Consent to Participate in the Study, Patients aged 35-85 years old, Patients with ASA class 1 and 2  
Exclusion: History of allergy or allergic reaction to each of the study drugs, History of head injury, Cardiovascular risk, Hypertension, Severe respiratory disease, Advanced liver disease, Epilepsy or history of seizure, Nervous system disorders, The presence of any tumor or brain metastasis, Use of any analgesic and anesthetic drugs, Chronic pain syndrome, Patients who are not satisfied to enter the study, Pregnant women

##### Intervention groups

Intervention group: Patients received fentanyl in 1.5 mg / kg dose In the group (E), they receive an etomidat at a dose of 0.1 mg / kg. If needed, 4 mg of the etomidate will be injected and recorded as a rescue dose. At the end of the dose, the total dose is recorded. In group (P), receive propofol at a dose of 0.5 mg/kg. If needed, 20 mg of propofol will be injected and recorded as a rescue dose. At the end of the dose, the total dose is recorded. In group (M), midazolam is given at a dose of 0.04 mg/kg. If needed, 2 mg of midazolam will be injected as a rescue dose. At the end of the dose, the total dose is recorded.

##### Main outcome variables

Sedation level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170809035601N10**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **retrospective**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

##### Registration date

2018-12-29, 1397/10/08

##### Registrant information

##### Name

Hamidreza Shetabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 2105

##### Email address

hamidshetabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-01, 1396/08/10

##### Expected recruitment end date

2018-06-30, 1397/04/09

##### Actual recruitment start date

2017-11-06, 1396/08/15

##### Actual recruitment end date

2018-06-30, 1397/04/09

##### Trial completion date

**Scientific title**

Comparison of fentanyl-etomidate, fentanyl-propofol and fentanyl-midazolam for sedation in phacoemulsification

**Public title**

The effect of sedation of fentanyl-etomidate, fentanyl-propofol and fentanyl-midazolam in phacoemulsification

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who are candidates for Phacoemulsification cataract surgery Patients who are satisfied to enter the study Patients aged 35-85 years old patients with ASA class 1 and 2

**Exclusion criteria:**

History of any allergy or allergic reaction to any of medications used in the study History of head injury High intraocular pressure or intracranial pressure Cardiovascular risk Hypertension Severe respiratory disease Advanced liver disease Epilepsy or history of seizure Nervous system disorders The presence of any tumor or brain metastasis Use of any analgesic and anesthetic drugs Chronic pain syndroms Patients who are not satisfied to enter the study Pregnant women

**Age**

From **35 years** old to **85 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **150**  
More than 1 sample in each individual  
Number of samples in each individual: **50**  
One sample at each participant  
Actual sample size reached: **99**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the operating room, based on a random number table, one of the compounds of fentanyl- etomidate, fentanyl-propofol and fentanyl -midazolam is given to patients.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, both the participants and the outcomes Assessor were blind to the allocation of the participants into groups of fentanyl- etomidate, fentanyl- propofol and fentanyl -midazolam . The study drugs were prepared in 4 syringes covered with aluminum foil, by an anesthesiologist who was not involved in data collection.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committe of Isfehan University of Medical Sciences

**Street address**

Isfehan University of Medical Sciences and Health Services, Building No.4, Research and Technology Deputy of University,Hezar Jarib Street, Isfahan town

**City**

Isfehan

**Province**

Isfehan

**Postal code**

8174673461

**Approval date**

2018-12-01, 1397/09/10

**Ethics committee reference number**

IR.MUI.MED.REC.1397.150

**Health conditions studied****1****Description of health condition studied**

Cataract surgery

**ICD-10 code**

H26.9

**ICD-10 code description**

Cataract surgery

**Primary outcomes****1****Description**

Sedation level

**Timepoint**

After induction of anesthesia, during the procedure every 5 minutes

**Method of measurement**

Modified ramsay sedation scale (RSS)

**Secondary outcomes****1****Description**

Mean Atrial Pressure

**Timepoint**

Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery

## Method of measurement

Pressure gauge

## 2

### Description

Oxygen saturation percentage

### Timepoint

Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery

### Method of measurement

Pulse oximetry

## 3

### Description

Heart rate

### Timepoint

Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery

### Method of measurement

Pulse oximetry

## 4

### Description

Adverse drug reaction

### Timepoint

Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery

### Method of measurement

Adverse drug reaction questionnaire

## 5

### Description

Recovery time

### Timepoint

From the end of the surgery to the time exit Recovery

### Method of measurement

Minute

## 6

### Description

Surgeon satisfaction

### Timepoint

End of surgery

### Method of measurement

Likert scale

## 7

### Description

Patient satisfaction

### Timepoint

End of Recovery

### Method of measurement

Likert scale

## Intervention groups

## 1

### Description

Intervention group: patients in group (E )received 0.1 mg/kg etomidate. In case of need, 4 mg etomidate will be injected as a rescue dose. At the end of the prescribed total dose is recorded.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: patients in group (P) received 0.5 mg/kg propofol. In case of need, 20 mg propofol will be injected as a rescue dose. At the end of the prescribed total dose is recorded.

### Category

Treatment - Drugs

## 3

### Description

Intervention group: patients in group (M) received 0.04 mg/kg midazolam. In case of need, 2 mg midazolam will be injected as a rescue dose. At the end of the prescribed total dose is recorded.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Faiz Hospital

#### Full name of responsible person

Hamidreza Shetabi

#### Street address

Faiz Hospital, Modares st

#### City

Isfahan

#### Province

Isfahan

#### Postal code

7346181764

#### Phone

+98 31 3445 2035

#### Email

hamidshetabi@med.mui.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghyegh Haghjoo Javanmard

#### Street address

Vice chancellor of research and technology of

university, Isfahan University of Medical Sciences,  
Hezarjarib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

sh\_haghjoo@med.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**

Isfahan University of Medical Sciences

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Feyz hospital, Modares st

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 8138

**Email**

hamidshetabi@med.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Assistant profesor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Email**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**City**

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**Province**

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**Postal code**

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**Phone**

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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**

The total potential data can be shared after  
unidentifiable people

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

Start the access period one year after the publication of  
results

**To whom data/document is available**

Only available for scholars working in academic and

academic centers

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

Use of data is permitted for the purpose of developing  
research on the use of the drug

**From where data/document is obtainable**

To the email address of the corresponding author

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

Within two weeks, the requested information will be  
provided to the applicant

**Comments**