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-etoimidate, 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.1

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

2018-06-30, 1397/04/09

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 phacoamulsification

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
Isfehan
Province
Isfehan
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
Isfehan

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
Assisstant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Feyz hospital, Modares st

City
Isfahan

Province
Isfehan

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
Assisstant profesor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Faiz hospital, Modares st.

City
Isfehan

Province
Isfehan

Postal code
7346181746

Phone
+98 31 3668 8138

Email
hamidshetabi@med.mui.ac.ir

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

Street address
Feyz hospital, Modares st

City
Isfahan

Province
Isfehan

Postal code
7346181764

Phone
+98 31 3668 8138

Email
hamidshetabi@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
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