Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of cardiovascular response to sedation with dexmedetomidine, midazolam and etomidatein phacoemulsification under local anesthesia

Protocol summary

Study aim
Selecting the best drug in terms of maximum efficacy in sedation and minimum rate of complications during and after surgery among the drugs studied.

Design
Clinical trials in two community-based and pragmatic groups with parallel groups, a total volume of 90,double blinded, and randomized

Settings and conduct
The use of three different drugs with specific doses in three groups and comparing their effect on the sedation level in cataract surgery by phacoamulsification in Feyz Hospital in Isfahan. The patient and Researcher unaware of which drugs are used for each patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 90 years undergoing cataract surgery using phacoemulsification methods under local anesthesia and sedation in the first and second classes of the American Anesthetic Association. Exclusion criteria: history of any allergy to the drug used in the design, history of drug addiction, alcohol, benzodiazepine and pregnancy, congestive heart failure, history of head trauma, glaucoma, hypotension, evidence of increased intracranial pressure, psychosis, schizophrenia, active upper respiratory tract infection , Asthma, chronic respiratory disease.

Intervention groups
Patients in the first group (group D) will receive dexmedetomidine and patients in the second group (group M) will receive midazolam-fentanyl and in the third group (group E) atomidite for sedation during surgery. The sample size in each group was 30 people

Main outcome variables
Sedation level; drug complications; pain intensity; Arterial blood pressure; oxygen saturation; heart rate; recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N20**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
hamidshetabi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-09-20, 1401/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of cardiovascular response to sedation with dexmedetomidine, midazolam and etomidatein phacoemulsification under local anesthesia

Public title
The effect of cardiovascular response to sedation with dexmedetomidine, midazolam and atomidite in cataract surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 35 to 85 years Patients who are candidates for phycoemolysis cataract surgery Patients undergoing local anesthesia and sedation in this surgery have Class 1 and 2 of the American Anesthesia Association Patients with controlled blood pressure

Exclusion criteria:
History of any allergy to the drug used in the design History of drug addiction, alcohol, benzodiazepine Pregnancy Congestive heart failure History of head trauma Glaucoma Hypotension Evidence of increased intracranial pressure Psychosis Schizophrenia Active upper respiratory tract infection Asthma Chronic respiratory disease

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The division of patients into two groups is based on a random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is double blinded.Patient and researcher are unaware of patient groups and type of medication.The medications are prepared by an anesthetist who is unaware of the grouping of patients and is worn by an aluminum foil and encoded by an anesthetist.Demographic information; Sedation level. The quality of pain relief and hemodynamic variables and complications are collected by a patient who is not aware of the type of drug and patient grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan Unoversity of medical sciences, Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-12-04, 1400/09/13

Ethics committee reference number
1400.674.IR.MUI.MED.REC

Health conditions studied

1

Description of health condition studied
Cataract surgery

ICD-10 code
H43.9

ICD-10 code description
Unspecified disorder of vitreous body

Primary outcomes

1

Description
Sedation level based on ramsay score

Timepoint
Every 5 minutes during surgery

Method of measurement
Ramsay score

Secondary outcomes

1

Description
Arterial pressure

Timepoint
Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

Method of measurement
Pressure gauge

2

Description
Oxygen saturation
Timepoint
Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes
Method of measurement
Pulse oximeter

3

Description
Heart rate
Timepoint
Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes
Method of measurement
Pulse oximeter

4

Description
Intensity of pain
Timepoint
Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes
Method of measurement
Universal Pain assessment tool

5

Description
recovery time
Timepoint
After completing the intervention until the withdrawal from the recovery
Method of measurement
Minute Numbers

Intervention groups

1

Description
Intervention group: In dexmedetomidine group (D), patients will receive 1 /g / kg of dexmedetomidine in 20 ml of normal saline for 10 minutes followed by infusion of dexmedetomidine at 0.5 /g / kg / h.
Category
Treatment - Drugs

2

Description
Intervention group: In the midazolam group (M) patients will receive 0.05 mg / kg of slow intravenous midazolam
Category
Treatment - Drugs

3

Description
Intervention group: In the atomidite group (E) they will receive 0.2mg / kg. In all three groups, 1.5mcg / kg for fentanyl analgesia and 0.5mg / kg propofol with a concentration of 5mg / ml is prescribed if more sedation is needed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz Hospital
Full name of responsible person
Hamidreza Shetabi
Street address
Feyz Hospital , Modares St
City
Isfahan
Province
Isfehan
Postal code
7346181746
Phone
+98 31 3445 2034
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
Shaqayeq Haghjooye Javanmard
Street address
Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
Sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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
73461-81764

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 Professor

Latest degree
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Other areas of specialty/work
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Isfahan

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Postal code
73461-81764

Phone
+98 31 3445 2034

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

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73461-81764

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Email
Hamidshetabi@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available