

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of cardiovascular response to sedation with dexmedetomidine, midazolam and etomidate in 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 phacoemulsification 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) etomidate 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 etomidate in phacoemulsification under local anesthesia

Public title

The effect of cardiovascular response to sedation with dexmedetomidine, midazolam and etomidate in cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 35 to 85 years Patients who are candidates for phacoemulsification 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 University of medical sciences, Hezar Jarib Street

City

Isfahan

Province

Isfahan

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

Isfahan

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

Isfahan

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
Isfahan
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
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Feyz hospital, Modares St
City
Isfahan

Province
Isfahan
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
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Feyz hospital, Modares St
City
Isfahan
Province
Isfahan
Postal code
73461-81764
Phone
+98 31 3445 2034
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