Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparative study of efficacy and side effects of combination Nesdonal - Fentanyl - Midazolam with Etomidate - Fentanyl - Midazolam for sedation of patients undergoing cataract surgery

Protocol summary

Study aim
Comparative study of efficacy and side effects of combination Nesdonal - Fentanyl - Midazolam with Etomidate - Fentanyl - Midazolam for sedation of patients undergoing cataract surgery at Feiz hospital in 1402

Design
This randomized clinical trial has two parallel groups, triple-blind, phase 3 on 52 patients. Random allocation software was used for randomization.

Settings and conduct
The type of study is a three-blind randomized clinical trial in the population of patients who are candidates for cataract surgery between 18 and 70 years old by phacoemulsification method in Feiz Hospital in 1401.The three-way blinding of the study: the patient, the data collector, and the data analyst do not know about injectable drugs. For the purpose of blinding, similar syringes are used without specific color and name and are covered with aluminum foil. After collecting the data until the end of the statistical analysis, one group is randomly called A group and the other B.

Participants/Inclusion and exclusion criteria
Entry criteria include: candidates for cataract surgery by emulsification method, having (ASA) between 1 and 3, age between 18 and 70 and consent to participate in the study. Conditions for not entering include: Parkinson's disease, claustrophobia, dyspenea, psychosis, acute cardiac ischemia in the last 3 months, history of narcotic drugs use, history of allergy to anesthetics, pregnancy, weighing more than 100 kg, and baseline blood pressure more than 180/110.

Intervention groups
First group: receiving Nesdonal - fentanyl - midazolam
The second group: receiving Etomidate - fentanyl - midazolam

Main outcome variables
Complications frequency; complications severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230715058780N1**
Registration date: **2023-07-28, 1402/05/06**
Registration timing: **prospective**

Last update: **2023-07-28, 1402/05/06**
Update count: **0**

Registration date
2023-07-28, 1402/05/06

Registrant information

Name
SEYEDSAEED HOSSEINI

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3580 3308

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-05, 1402/05/14

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of efficacy and side effects of combination Nesdonal - Fentanyl - Midazolam with Etomidate - Fentanyl - Midazolam for sedation of patients undergoing cataract surgery

Public title
Comparative study of efficacy and side effects of combination Nesdonal - Fentanyl - Midazolam with Etomidate - Fentanyl - Midazolam for sedation of patients undergoing cataract surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Cataract surgery candidates for emulsification method Having (ASA) between 1 and 3 Age between 18 and 70 years Consent to participate in the study

Exclusion criteria:
Parkinson's Occurrence of acute cardiac ischemia in the last three months Having a history of narcotic drugs use Having a history of allergy to anesthetics Pregnancy Weighing more than one hundred kilograms Baseline blood pressure greater than 180/110 Dyspenea Psychosis

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of each day, samples are selected based on the inclusion criteria and after informed consent, random allocation is done based on the file number by random allocation software. People are divided into two groups A and B, for the purpose of blinding, only one reliable person, other than the researcher and data collector, is aware of the type of intervention, then each group is printed in two separate but similar lists. The type of sedation and the people in each group are confirmed by respected anesthesia experts. The data collector only knows the patients by their file number and has no knowledge of the type of intervention. Also, these data are still available to the data analyst in two groups, nicknamed A and B, and the type of intervention remains with the designated person until the end of the analysis.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The three-way blinding of the study in terms of: 1) the patient does not know the type of injectable drugs. 2) The data collector has no knowledge of injectable drugs. 3) The data analyst has no knowledge of which group the data belongs to. For the purpose of blinding, similar syringes are used without a specific color and name and are covered with aluminum foil, and after collecting the data until the end of the statistical analysis, Randomly, one group is called A and the other B

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
Research and Technology Vice-Chancellorm., Building No. 4., Isfahan University of Medical Sciences and Health Care Services., Hazar Jarib St

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esfahan

Province
Isfehan

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8174673461

Approval date
2023-04-01, 1402/01/12

Ethics committee reference number
IR.MUI.MED.REC.1402.015

Health conditions studied

1

Description of health condition studied
Cataract surgery

ICD-10 code
H25.0

ICD-10 code description
Age-related incipient cataract

Primary outcomes

1

Description
Blood pressure

Timepoint
before receiving the drugs, after receiving, 5, 10, 20 minutes after the start of surgery and during recovery, first immediately and then every 15 minutes until leaving the recovery

Method of measurement
Operating room monitoring device

2

Description
Respiratory rate per minute
Timepoint
before receiving the drugs, after receiving, 5, 10, 20 minutes after the start of surgery and during recovery, first immediately and then every 15 minutes until leaving the recovery
Method of measurement
Operating room monitoring device

3

Description
Heart rate per minute
Timepoint
before receiving the drugs, after receiving, 5, 10, 20 minutes after the start of surgery and during recovery, first immediately and then every 15 minutes until leaving the recovery
Method of measurement
Operating room monitoring device

4

Description
Blood oxygen saturation percentage
Timepoint
before receiving the drugs, after receiving, 5, 10, 20 minutes after the start of surgery and during recovery, first immediately and then every 15 minutes until leaving the recovery
Method of measurement
Operating room monitoring device

5

Description
Determining and comparing the average length of stay in recovery Community Verified icon
Timepoint
After transfer to recovery until the end
Method of measurement
timer

6

Description
Determining and comparing the frequency of sedation
Timepoint
At the time of receiving the drugs and 5, 10, 20 minutes after the start of the surgery Community Verified icon
Method of measurement
Determining sedation with the Ramsay-Sedation-Scale

7

Description
Determining and comparing the frequency of surgeon satisfaction Community Verified icon
Timepoint
End of surgery
Method of measurement
CHECK LIST

Secondary outcomes

1

Description
Determining and comparing the frequency of intramuscular metoclopramide consumption in recovery
Timepoint
After exiting recovery
Method of measurement
Determining nausea based on Baxter Retching Faces and metoclopromide injection in scores higher than 6 and counting doses

Intervention groups

1

Description
Intervention group: Intervention group: The FIRST group is first injected with midazolam and fentanyl intravenous bolus with the following dose: fentanyl 1 Microg/Kg, midazolam 0.02 Mg/Kg, then after 3 minutes intravenous bolus Nesdonal is injected with the following dose: 3mg/kg
Category
Treatment - Drugs

2

Description
Intervention group :The second group is first injected with intravenous midazolam and fentanyl bolus with the following dose: midazolam 0.02 mg/Kg, fentanyl 1 Microg/Kg, then after 3 minutes, Etomidate is injected as an infusion: 0.03mg/kg/h
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Educational and Therapeutic Center
Full name of responsible person
Mitra Jabal Ameli
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Sponsors / Funding sources

1

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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
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
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Position
Professor of Anesthesiology
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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