Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

A comparison between the effects of midazolam, propofol, and dexmedethomidine on hemodynamics variation in patients undergoing cataract surgery under local anesthesia

Protocol summary

Study aim
Comparison of the effect of midazolam, propofol and dexmedetomidine for sedation of patients during cataract surgery under local anesthesia.

Design
Clinical trial without control group, with parallel groups, double-blind, randomized, on 90 patients. A table of random numbers is used for randomization.

Settings and conduct
We use the double-blind method in which the patient and the researchers related to the study were not aware of the type of study group. anesthesia) is done in such a way that according to the three types of injectable drugs, three types of syringes are used, and only the anesthesiologist knows the type of contents of the syringes and the drugs received by the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for surgery, ASA class 2 and 3 patients, Patients in the age range of 18-90 years Exit criteria: The patient is pregnant, Occurrence of myocardial infarction in the last three months, History of reaction to benzodiazepine and dexmedetomidine drugs,

Intervention groups
we will have three intervention groups of 30 people, in all three intervention groups, having a peripheral IV line with a diameter of 20 and fluid therapy (receiving 200-250 cc of normal saline serum) before and during the operation is the same for all patients. will be done. In all three intervention groups, before the preparation and drape of the patient, the target eye will be anesthetized with two drops of 0.5% tetracaine before the operation. Then, the intervention group will receive one midazolam drug, the intervention group will receive two propofol drugs, and the intervention group will receive three dexmedomidine drugs.

Main outcome variables
Hemodynamic changes including heart rate, systolic and diastolic blood pressure and arterial blood oxygen saturation level

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20221020056250N1**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date
2022-12-07, 1401/09/16

Registrant information

Name
Seyed esmaeil Hatami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3222 6727

Email address
ss_hatami2011@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2022-12-14, 1401/09/23

Actual recruitment start date

2022-12-14, 1401/09/23

Actual recruitment end date

2022-12-14, 1401/09/23

Trial completion date

2022-12-22, 1401/10/01

Scientific title

A comparison between the effects of midazolam, propofol, and dexmedethomidine on hemodynamics variation in patients undergoing cataract surgery under local anesthesia

Public title

Investigating the effects of three drugs, midazolam, propofol and dexmedetomidine, on hemodynamic changes in cataract surgery patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for surgery ASA class 2 and 3 patients patients in the age range of 18-90 years

Exclusion criteria:

Patients aged less than 18 years and more than 90 years
The patient is pregnant

Age

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

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **110**
Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple random allocation method will be used using a table of random numbers, so that in order to hide it, we used the double-blind method, so that neither the patient nor the researchers related to the patients were aware of the type of study group and the selection of the patient. His group and the type of medicine received will be done by one of the researchers not related to the patient (the person injecting the medicine who is an anesthesiologist).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, we have used the double-blind method that the patient and the researchers related to the study were not aware of the type of study group, patient selection, patient grouping and the type of drug received by one of the researchers not related to the patient (injector drug, which is an anesthesiologist) was done in such a way that according to the three types of injectable drugs, three types of syringes were used, and only the anesthesiologist was aware of the type of contents of the syringes and the drugs received by the patients.

Placebo

Not used

Assignment

Parallel

Other design features

ندارد

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan Medical School

Street address

Golestan university of medical sciences, Hirkan Blvd, Gorgan, Golestan, Iran.

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.GOUMS.REC.1400.023

Health conditions studied

1

Description of health condition studied

Cataract surgery

ICD-10 code

H59.0

ICD-10 code description

Keratopathy (bullous aphakic) following cataract surgery

Primary outcomes

1

Description

Blood pressure measurement

Timepoint

Blood pressure before the injection of sedative drugs in each group, then 3 minutes after the injection of sedative drugs, and after that, the result every 5 minutes until the end of the surgery, and finally after delivery to recovery, every 15 minutes for an hour. They are measured so that the patient is delivered to the desired department

Method of measurement

The blood pressure of all patients will be taken by an automatic sphygmomanometer from the arm opposite to the surgical site

2

Description
Arterial blood oxygen
Timepoint
Blood pressure before the injection of sedative drugs in each group, then 3 minutes after the injection of sedative drugs, and after that, the result every 5 minutes until the end of the surgery, and finally after delivery to recovery, every 15 minutes for an hour. They are measured so that the patient is delivered to the desired department
Method of measurement
During the operation, all patients are examined for arterial blood oxygen saturation percentage while receiving 6 liters of oxygen per minute, and this measurement is done with a pulse oximeter device.

3

Description
nausea and vomiting
Timepoint
Blood pressure before the injection of sedative drugs in each group, then 3 minutes after the injection of sedative drugs, and after that, the result every 5 minutes until the end of the surgery, and finally after delivery to recovery, every 15 minutes for an hour. They are measured so that the patient is delivered to the desired department
Method of measurement
Vomiting and nausea of the patient during the operation, if observed, is recorded by mentioning the number.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: midazolam drug with a sedative dose of 100-25 µg/kg is injected as a intravenous bolus once before surgery for one minute.
Category
Treatment - Drugs

2

Description
The second intervention group: propofol with a low sedation dose, 25-100 µg/kg, is injected as a intravenous bolus once before surgery for one minute.
Category
Treatment - Drugs

3

Description
The third intervention group: dexmedetomidine with a low sedation dose of 0.5-1 µg/kg is injected as a intravenous bolus once before surgery for one minute.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5 Azar Educational and Therapeutic Center of Gorgan
Full name of responsible person
Mohammad reza Akbari
Street address
Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 915 584 8214
Email
mr.akbari.1344@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Beigom Mirbehbahani
Street address
Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 911 171 5216
Email
n.mirbehbahani@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Reza Akbari
Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.
City
Gorgan
Province
Golestan
Postal code
4934174515.
Phone
+98 58 3222 2683
Email
mr.akbari.1344@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Seyede Mahrokh Alinaghimaddah
Position
Assistant Professor of Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 58 3222 2683
Email
mitramaddah2000@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Seyede Mahrokh Alinaghimaddah
Position
Assistant Professor of Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 58 3222 2683
Email
mitramaddah2000@yahoo.com

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