

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

A comparison between the effects of midazolam, propofol, and dexmedetomidine 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 dexmedetomidine 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)

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+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 dexmedetomidine 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

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Golestan University of Medical Sciences and Health Services, Hirkan Blvd, Gorgan, Golestan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Narges Beigom Mirbehbahani

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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

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

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Assistant Professor of Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Province

Golestan

Postal code**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