Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of dexmedetomidine and propofol for maintenance anesthesia in cataract surgery

Protocol summary

Study aim
Comparison of dexmedetomidine and propofol for maintaining anesthesia during cataract surgery

Design
The clinical trial has a control group, with parallel groups, double-blind, Random allocation by permutation block method, phase 2 on 60 patients. For randomization, permutation blocks of six will be used.

Settings and conduct
This study will be conducted on the population of people with cataracts admitted to Heshmatieh Sabzevar Hospital. Patients are randomly assigned into three treatment groups using permutation blocks of six: propofol group, dexmedetomidine, and control group. Routine treatment is considered for the control group. Then, in the first group, dexmedetomidine is added to routine intravenous drugs, and in the second group, propofol is added to routine intravenous drugs. Hemodynamic symptoms (BP, PR, SPO2) are monitored in 5 time periods, including admission to the operating room, before anesthesia, immediately after, 15 minutes later, and during recovery. In addition, blinding is done in a double-blind manner (therapist and the outcome assessor).

Participants/Inclusion and exclusion criteria
obtaining informed consent, At least 60 years old, the absence of other eye diseases: the lack of drug sensitivity, the absence of underlying diseases

Intervention groups
Three treatment groups include propofol, dexmedetomidine, and a control group

Main outcome variables
Complications after anesthesia (nausea, dizziness, etc.); the length of time the patient remains in recovery; the amount of receiving narcotic painkillers; incidence and severity of delirium; Duration of patient sedation during cataract surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220921056014N1**
Registration date: **2023-02-17, 1401/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-17, 1401/11/28**
Update count: **0**

Registration date
2023-02-17, 1401/11/28

Registrant information
Name
Sara Dadsetan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3760 7356
Email address
dadsetan.sara1997@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-22, 1401/09/01
Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of dexmedetomidine and propofol for maintenance anesthesia in cataract surgery

Public title
Comparing the effects of dexmedetomidine and propofol in cataract surgery anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The need for cataract surgery Consent to participate in the study No other eye diseases No history of cataract surgery Lack of drug sensitivity Obtaining an anesthesiologist's license Not having underlying diseases At least 60 years old
Exclusion criteria:
Congenital cataract
Age
From **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be done by the permutation block method. Blocks of six will be used. In this method, A and B represent the people who receive two interventions and C means the person who is placed in the control group. Considering the block of 6; AABBCC code 0, ABCABC code 1, ABCBAC code 2, BACABC code 3, BBCCAA code 4, and BACBA C code 5. Then, using the table of random numbers, we randomly choose a starting point and consider 10 numbers in a row or column. Therefore, by selecting 10 numbers from the table, it will be determined how to allocate a total of 60 people into 3 groups. Randomization tools are cards marked with three letters A, B, and C. Envelopes will be used to conceal the allocator from the type of card.
Blinding (investigator's opinion)
Double blinded
Blinding description
Allocation of treatment is done by a person who is unaware of the treatment assigned to all three groups. In this case, cards are provided to the treatment allocator who is not aware of their content. The evaluation of the outcome will be done by a doctor who is not aware of the type of drug-assigned to each group (a doctor other than the treating doctor). In the data analysis, the help of the statistical consultant will be taken, who will not have any information about the type of treatment received by the people. Because during anesthesia, the person is exposed to the drug and is not aware of the type of injected drug, so even though part of the outcome is subjective (measured through VAS), there is no need to blind the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2022-08-13, 1401/05/22
Ethics committee reference number
IR.MEDSAB.REC.1401.035

Health conditions studied

1

Description of health condition studied
Cataract surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
blood pressure
Timepoint
5 time periods including admission to the operating room, before anesthesia, immediately after, 15 minutes later, and during recovery
Method of measurement
Mercury pressure gauge

2

Description
Respiratory Rate
Timepoint

5 time periods including admission to the operating room, before anesthesia, immediately after, 15 minutes later, and during recovery

Method of measurement

Timer

3

Description

Normal levels of oxygen saturation (SpO2)

Timepoint

5 time periods including admission to the operating room, before anesthesia, immediately after, 15 minutes later, and during recovery

Method of measurement

Pulse oximeter

4

Description

intensity of pain

Timepoint

2 time periods before anesthesia, after consciousness in recovery

Method of measurement

Visual Pain Scale Questionnaire (VAS)

5

Description

Nausea, vomiting and dizziness

Timepoint

A period of time after surgery in recovery

Method of measurement

check list

6

Description

delirium

Timepoint

A period of time after surgery in recovery

Method of measurement

check list

7

Description

The time it takes to wake up

Timepoint

A period of time after surgery in recovery

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Routine treatment, which includes receiving the usual protocol (a combination of lidocaine with a dose of 1 mg/kg, atracurium with a dose of 0.3 mg/kg, and fentanyl with a dose of 1 mcg/kg) in the form of intravenous injection and then using a mask and LMA for patients, is done.

Category

Treatment - Drugs

2

Description

Intervention group 1: routine drugs of the control group plus dexmedetomidine drug with a dose of 1 mcg/KG.

Category

Treatment - Drugs

3

Description

Intervention group 2: routine drugs of the control group plus the drug propofol at a dose of 1 mg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatieh Sabzevar Medical Education Center

Full name of responsible person

Sara Dadsetan

Street address

Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 915 582 2604

Email

dadsetan.sara1997@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Manijeh Yosefi Moghadam

Street address

Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town

City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
ymanijeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Manijeh Yosefi Moghadam
Position
Assistant Professor, Medical Specialist, Academic Staff
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
ymanijeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Manijeh Yosefi Moghadam
Position
Assistant Professor, Medical Specialist, Academic Staff
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
ymanijeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Sara Dadsetan
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
dadsetan.sara1997@gmail.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
Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

-

When the data will become available and for how long

No

To whom data/document is available

No

Under which criteria data/document could be used

No

From where data/document is obtainable

No

What processes are involved for a request to access data/document

No

Comments