

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; AABCC 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