Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The effect of intravenous infusion of remifentanil and dexmedetomidine on hemodynamic changes and pain in patients undergoing cataract surgery

Protocol summary

Study aim
Determining the effect of intravenous infusion of remifentanil and dexmedetomidine on hemodynamics and pain in patients undergoing cataract surgery.

Design
A clinical trial with two groups receiving dexmedetomidine and remifentanil, with parallel groups, double-blind, randomized using blocks of six, phase 3 on 122 patients.

Settings and conduct
Patients referred to Amirkabir Arak Hospital operating room for cataract surgery will be divided into groups R (recipients of remifentanil) and group D (recipients of dexmedetomidine). The medications are prepared by the anesthesiologist in similar syringes and given to the nurse anesthetist who does not know about the type of medications, then the medications will be administered by the nurse anesthetist who is a colleague of the project and finally the questionnaires of the project will be completed by her. patients do not know about the intervention, so the study is double-blind.

Participants/Inclusion and exclusion criteria
All candidates for cataract surgery referring to Amir Kabir Arak Hospital, filling in informed consent forms by patients, patients aged 25 to75 years, American Society of Anaesthesiologists' (ASA) classification of Physical Health I & II, candidate patients for local anesthesia

Intervention groups
Dexmedetomidine recipient, Remifentanil recipient

Main outcome variables
Determining the hemodynamic parameters of patients, determining the Richmond Agitation and Sedation Scale (RASS) in recovery, determining the Visual Analogue Scale VAS in recovery, determining the satisfaction of the surgeon during the surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220302054164N2**
Registration date: **2023-01-19, 1401/10/29**
Registration timing: **prospective**

Last update: **2023-01-19, 1401/10/29**
Update count: **0**

Registration date
2023-01-19, 1401/10/29

Registrant information

Name
Safoora Omidvar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intravenous infusion of remifentanil and dexmedetomidine on hemodynamic changes and pain in patients undergoing cataract surgery

Public title
The effect of intravenous infusion of remifentanil and dexmedetomidine on hemodynamic changes and pain in patients undergoing cataract surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients referred to Amirkabir Arak Hospital for cataract surgery signing informed consent by patients Patients age 25-75 years American Society of Anesthesiologists (ASA) physical status classification I & II Candidates of local anesthesia

Exclusion criteria:

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **122**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, the patients who meet the criteria of the study will be selected by available sampling, then they will be assigned to two intervention groups, dexmedetomidine (D) and remifentanil (R), using random permuted blocks. In order to randomize patients, 17 blocks of 6 will be used: RDDRDR, RDRDRD, DRRDDR, etc. D indicates dexmedetomidine group and R indicates remifentanil group. The order of the blocks will be randomly determined using a table of random numbers, and then the patients will be assigned to remifentanil and dexmedetomidine groups based on the blocks. One of the researchers who will not play a role in data collection will do the sequence of random allocation of blocks. The intervention will be done by other researchers. Blinding will be done with the help of a trained person who does not know about the allocation of patients in groups, and the measurements will be done by this person.

Blinding (investigator's opinion)
Double blinded

Blinding description
The medications will be prepared by the anesthesiologist in charge of the research in syringes of the same size and color (only he knows the type and dosage of the drugs) and given to the anesthetist who is unaware of the type and dosage of the drug in the syringe, and finally, the questionnaire will be filled in by the same anesthetist, so this study will be double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Science

Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2021-12-19, 1400/09/28

Ethics committee reference number
IR.ARAKMU.REC.1400.273

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Hemodynamic variables based on the questionnaire

Timepoint
During surgery and recovery

Method of measurement
monitoring devices

2

Description
Emergence agitation

Timepoint
Recovery room

Method of measurement
Richmond Agitation and Sedation Scale (RASS)

3

Description
Pain score
Timepoint
recovery
Method of measurement
The Visual Analogue Scale (VAS)

4

Description
Surgeon satisfaction
Timepoint
During surgery
Method of measurement
Asking the surgeon

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexmedetomidine recipient Receiving ./5 µg/kg/h of dexmedetomidine from Elixir company using an infusion pump from the onset of induction of anesthesia to the end of surgery
Category
Treatment - Drugs

2

Description
Intervention group: Remifentanil recipient Receiving 2 µg/kg/h of remifentanil from Elixir company using an infusion pump from the onset of induction of anesthesia to the end of surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir hospital
Full name of responsible person
Alireza Kamali
Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Safoora Omidvar
Position
Professor
Latest degree
Master
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after de-identifying the participants
When the data will become available and for how long
Access starts after the publication of the article
To whom data/document is available
researchers and students
Under which criteria data/document could be used
In order to use the results
From where data/document is obtainable
The person in charge of the project with the mentioned specifications
What processes are involved for a request to access data/document
The request is sent by email to the correspond author with the address S_omidvar1991@yahoo.com and the information is provided to the requester.
Comments