Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Dexmedetomidine Versus Ketamine-Propofol combination versus Propofol for Sedation in Cataract Surgery

Protocol summary

Study aim

Comparison of Dexmedetomidine and Propofol with Ketamine-Propofol combination for Sedation in Cataract Surgery

Design

The study of the two-course clinical trial of 96 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Candidates for cataract surgery in Amirkabir Hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age 18 to 85 years, both sexes ,candidate for cataract surgery ,absence of mental disorders ,lack of chronic history of sedatives ,no alcohol and drugs ,lack of allergy to the drugs used ,absence of severe obstructive pulmonary disease and name ,no history of heart disease, heart block and bradycardia ,absence of systolic blood pressure less than 90 mm Hg ,absence of severe liver failure ,absence of uncontrolled diabetes ,absence of cerebrovascular diseases Exclusion criteria:Patient dissatisfaction ,existence of any complication during sedation that leads to change of anesthesia schedule or cancellation of surgery.

Intervention groups

Intervention group 1: Dexmedetomidine dose of 0.5 microgram in kilogram will injected intravenously to patients in 10 minutes. Intervention group: 20 milliliter of propofol and 2 milliliter of ketamine and 28 milliliter of normal saline are mixed. The resulting solution contains 4 milligram of propofol and 2 milligramof ketamine. 125. 0 milliliter in kilogram in ten minutes Intervention group 3: They receive 0.3 milligram in kilogram of propofol by intravenous bolus injection and then 0.5 milligram in kilogram per hour by slow intravenous infusion.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N148**
Registration date: **2020-09-21, 1399/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**
Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name
Fariba Farokhi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 86 3222 2003
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2021-07-01, 1400/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Dexmedetomidine Versus Ketamine-Propofol combination versus Propofol for Sedation in Cataract Surgery

Public title
Comparison of Dexmedetomidine Versus Ketamine-Propofol combination versus Propofol for Sedation in Cataract Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 85 years Both sexes Candidate for cataract surgery Absence of mental disorders Lack of chronic history of sedatives No alcohol and drugs Lack of allergy to the drugs used Absence of severe obstructive pulmonary disease and name No history of heart disease, heart block and bradycardia Absence of systolic blood pressure less than 90 mm Hg Absence of severe liver failure Absence of uncontrolled diabetes Absence of cerebrovascular diseases
Exclusion criteria:
Patient dissatisfaction Existence of any complication during sedation that leads to change of anesthesia schedule or cancellation of surgery.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with random allocation with envelopes in 2 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is clinical trial.Outcome elevator and analyzer and participant are blind (double blind).Outcome elevator and analyzer and participant don't aware from grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.ARAKMU.REC.1399.130

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
Pain
Timepoint
Every 5 minutes in surgery and recovery
Method of measurement
Visual analog scale pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Dexmedetomidine dose of 0.5 microgram in kilogram will injected intravenously to patients in 10 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: 20 milliliter of propofol and 2 milliliter of ketamine and 28 milliliter of normal saline are mixed. The resulting solution contains 4 milligram of propofol and 2 milligramof ketamine. 0.125 milliliter in kilogram in ten minutes

Category

Treatment - Drugs

3

Description

Intervention group 3: They receive 0.3 milligram in kilogram of propofol by intravenous bolus injection and then 0.5 milligram in kilogram per hour by slow intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr HAlireza Kamali

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Amirkabir hospital, Parastar square, Arak

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Sponsors / Funding sources

1

Sponsor

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

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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