Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of sedation and hemodynamic changes resulting from administration of dexmedetomidine, ketamine and Etomidate with propofol during cataract surgery by Phacoemulsification method

Protocol summary

Study aim
Comparison of sedation and hemodynamic changes resulting from administration of dexmedetomidine, ketamine and Etomidate with propofol during cataract surgery by Phacoemulsification method

Design
The study of the two-course clinical trial of 128 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Candidates cataract surgery in Amirkabir Hospital in Arak are divided into 4 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:Candidate for cataract surgery by Fico method, age 35 to 85 years, absence of mental disorders, lack of history of chronic use of sedatives, no alcohol and drugs, absence of severe obstructive pulmonary disease and asthma, no history of heart disease, heart block and bradycardia, absence of systolic blood pressure less than 90 mm Hg, absence of severe liver and renal failure, absence of uncontrolled diabetes, absence of cerebrovascular diseases Exclusion criteria: patient dissatisfaction, existence of any complication during sedation that leads to a change in the method of anesthesia used or cancellation of surgery

Intervention groups
Intervention group: Dexmedetomidine is administered intravenously at a dose of 0.5 µg / kg. (Madonex ampoule 100 micro grams per millilitre made by Exir Pharmaceutical Company - Iran) Intervention group: 0.1 mg / kg of Etomidate is given to patients. (Made by Abureihan Pharmaceutical Company - Iran) Intervention group: 0.5 mg / kg ketamine is administered intravenously. (Made by Rotex Medica - Germany) (Rotexmedica GmbH Arzneimittelwerk) Placebo group: Receive routine treatment with placebo.

Main outcome variables
Relaxation, pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N156**
Registration date: **2021-04-25, 1400/02/05**
Registration timing: **prospective**

Last update: **2021-04-25, 1400/02/05**
Update count: **0**

Registration date
2021-04-25, 1400/02/05

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedation and hemodynamic changes resulting from administration of dexmedetomidine, ketamine and Etomidate with propofol during cataract surgery by Phacoemulsification method

Public title

Comparison of sedation and hemodynamic changes resulting from administration of dexmedetomidine, ketamine and Etomidate with propofol during cataract surgery by Phacoemulsification method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for cataract surgery by Fico method Age 35 to 85 years Absence of mental disorders Lack of history of chronic use of sedatives No alcohol and drugs Absence of severe obstructive pulmonary disease and asthma No history of heart disease, heart block and bradycardia Absence of systolic blood pressure less than 90 mm Hg Absence of severe liver and renal failure Absence of uncontrolled diabetes Absence of cerebrovascular diseases

Exclusion criteria:

Patient dissatisfaction

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in4 groups A and B and C and D. 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

Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping.

Placebo

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

2021-03-03, 1399/12/13

Ethics committee reference number

IR.ARAKMU.REC.1399.339

Health conditions studied

1

Description of health condition studied

Cataract surgery

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Sedation

Timepoint

Every 5 minutes during surgery and in recovery and 1, 2 and 4 hours after surgery

Method of measurement

Ramsay score

2

Description

Pain

Timepoint

During surgery every 5 minutes and during recovery and

1, 2 and 4 hours after surgery

Method of measurement

Visual analog pain score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexmedetomidine is administered intravenously at a dose of 0.5 µg / kg. (Madonex ampoule 100 micro grams per millilitre made by Exir Pharmaceutical Company - Iran)

Category

Treatment - Drugs

2

Description

Intervention group: 0.1 mg / kg of Etomidate is given to patients. (Made by Abureihan Pharmaceutical Company - Iran)

Category

Treatment - Drugs

3

Description

Intervention group: 0.5 mg / kg ketamine is administered intravenously. (Made by Rotex Medica - Germany) (Rotexmedica GmbH Arzneimittelwerk)

Category

Treatment - Drugs

4

Description

Control group: Receive routine treatment with placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Hesamodin Modir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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 Esmaeel Moshiri

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