

# 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)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### 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 in 4 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 committee of Arak University of Medical Sciences

##### Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, 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

###### Street address

Amirkabir hospital, Parastar square, Arak

###### City

Arak

###### Province

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###### Postal code

3814957558

###### Phone

+98 86 3222 2003

###### Fax

+98 86 3222 2003

###### Email

modir.he@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Arak University of Medical Sciences

###### Full name of responsible person

Dr Alireza Kamali

###### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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###### Email

alikalaliir@yahoo.com

##### 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

**Street address**

Shahid Shirodi street, Valiasr square, Valiasr hospital

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hesamedin Modir

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Bardia Moghisseh

**Position**

medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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+98 86 3222 2003

**Email**

Bardiamoghisseh@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**

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