

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A comparative study of two sedation methods during cataract surgery with two combinations of sodium thiopental and ketamine vs propofol and ketamine under local anesthesia in 60 patients who are candidates for cataract surgery due to old age and the effectiveness and side effects of this combination

Protocol summary

Study aim

Determining the effectiveness of the most studied drugs with the least side effects

Design

Patients are randomly divided into two groups A and B by random allocation software. In one group, the combination of sodium thiopental and ketamine is used, and in the other group, the combination of propofol and ketamine is used. There are 30 people in each group.

Settings and conduct

A three-blind clinical trial at Faiz Medical Education Center in 2022-2023

Participants/Inclusion and exclusion criteria

Conditions of non-entry: history of alcohol addiction, smoking, drugs, seizures and sensitivity to drugs used in research Entry requirements: age 30 to 70 years old - cataract caused by aging - ASA 1,2,3

Intervention groups

The combination of sodium thiopental and ketamine compared with propofol and ketamine

Main outcome variables

Choosing one of the medicinal combinations of sodium thiopental and ketamine or propofol and ketamine for sedation during cataract surgery is to achieve higher quality in surgery and fewer complications after surgery, considering achieving the desired level of sedation and limiting the patient's activity during surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100926004819N6**

Registration date: **2023-01-27, 1401/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-27, 1401/11/07**

Update count: **0**

Registration date

2023-01-27, 1401/11/07

Registrant information

Name

Saied Morteza Heidari Tabaei Zavareh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1267 6415

Email address

m_heidari@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-09, 1401/10/19

Expected recruitment end date

2023-02-08, 1401/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of two sedation methods during cataract surgery with two combinations of sodium thiopental and ketamine vs propofol and ketamine under local anesthesia in 60 patients who are candidates for cataract surgery due to old age and the effectiveness and side effects of this combination	
Public title	Comparative investigation of two sedation methods during cataract surgery with two combinations of sodium thiopental and ketamine vs propofol and ketamine under local anesthesia.
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Candidate patients for cataract surgery due to old age Consent to participate in the study Age between 30 and 70 years ASA1/2/3 Exclusion criteria: Need general anesthesia Seizures and response to study drugs High risk of surgery such as monocular or traumatic patients History of alcoholism, smoking, drugs
Age	From 30 years old to 70 years old
Gender	Both
Phase	2
Groups that have been masked	- Participant - Care provider - Investigator
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is done by simple randomization method. The randomization unit is individual and layered randomization is not used. The randomization tool is Randomize Allocation software.
Blinding (investigator's opinion)	Triple blinded
Blinding description	In this study, one group of patients received ketamine and propofol, and the other group received ketamine and sodium thiopental. The study is triple-blind, which means the patient does not know about his group, the person who collects the data does not know which patient received which combination, and the statistical analyst does not know about the groups either.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	ethics committee of isfehan university of medical science
Street address	feiz hospital
City	isfehan
Province	Isfehan
Postal code	۸۱۷۴۶۷۳۴۶۱
Approval date	2022-05-27, 1401/03/06
Ethics committee reference number	IR.MUI.MED.REC.1401.098
Health conditions studied	
<u>1</u>	
Description of health condition studied	senile cataract
ICD-10 code	T88.5
ICD-10 code description	Other complications of anesthesia
Primary outcomes	
<u>1</u>	
Description	Appropriate sedation during surgery with monitoring of vital signs during surgery
Timepoint	0, 10, 20, 30, 40, 60 minutes in the operating room and 0, 15, 30 minutes in recovery
Method of measurement	monitoring device
<u>2</u>	
Description	Pain intensity during and after surgery
Timepoint	During recovery and during surgery
Method of measurement	questionnaire
<u>3</u>	
Description	Consent of the surgeon and the patient
Timepoint	During recovery and during surgery
Method of measurement	questionnaire

4

Description

drug's side effect

Timepoint

in recovery room , after being alert

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group, after placing the patient on the surgical bed, ambulatory monitoring of blood pressure, ECG, pulse oximetry and capnograph is established for monitoring the patient during the operation. Systolic and diastolic blood pressure, arterial blood oxygen saturation, end-expiratory CO2 and heart rate are measured and recorded. Then, to start sedation, the combination of fentanyl with a dose of 1μ/Kg, propofol with a dose of 2mg/kg/lit and ketamine with a dose of 0.3mg/kg will be used, then during surgery to maintain sedation with ketamine with a dose of 0.3mg/kg every five minutes and Thiopental sodium is found at a dose of 0.3 mg/kg every five minutes.

Category

Rehabilitation

2

Description

Intervention group: The second group, after placing the patient on the surgical bed, ambulatory monitoring of blood pressure, ECG, pulse oximetry and capnograph is established for monitoring the patient during the operation. Systolic and diastolic blood pressure, arterial blood oxygen saturation, end-expiratory CO2 and heart rate are measured and recorded. Then, to start sedation, fentanyl with a dose of 1μ/Kg, propofol with a dose of 2mg/kg/lit, and ketamine with a dose of 0.3mg/kg will be used, then during surgery to maintain sedation with a combination of ketamine with a dose of 0.3mg/kg every five minutes. and propofol at a dose of 2 mg/kg every five minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Saied Morteza Heidari Tabaei Zavareh

Street address

No. 1, Ayatollah Modares Street, Qods Square, Isfahan

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Phone

+98 921 114 5026

Email

fatemeh.sadat075@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saied Morteza Heidari Tabaei Zavareh

Street address

Hazar Jarib - Isfahan University of Medical Sciences - building number 4

City

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Province

Isfahan

Postal code

8174673461

Phone

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Email

research@mui.ac.ir

Web page address

<https://research.mui.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Saied Morteza Heidari Tabaei Zavareh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

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

Esfahan University of Medical Sciences

Full name of responsible person

Saied Morteza Heidari Tabaei Zavareh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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

Esfahan University of Medical Sciences

Full name of responsible person

Saied Morteza Heidari Tabaei Zavareh

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

The access period starts 12 months after the publication of the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

If used for other studies

From where data/document is obtainable

If you request access to the documents, send a message to the email below. fatemeh .sadat075@gmail.com

What processes are involved for a request to access data/document

Approval of Research Committee and Ethics Committee of Isfahan University of Medical Sciences

Comments