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

1

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

1

Description of health condition studied

senile cataract

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

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

2

Description

Pain intensity during and after surgery

Timepoint

During recovery and during surgery

Method of measurement

questionnaire

3

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
City
isfehan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
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
isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
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
Isfahan Province, Isfahan, Qods Square, Ayat A...
Modares St., No. 1
City
isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 921 114 5026
Email
fatemeh.sadat075@gmail.com

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
Street address
Isfahan Province, Isfahan, Qods Square, Ayat A...
Modares St., No. 1
City
isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 921 114 5026
Email
fatemeh.sadat075@gmail.com

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
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Isfahan Province, Isfahan, Qods Square, Ayat A...
Modares St., No. 1
City
isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 921 114 5026
Email
fatemeh.sadat075@gmail.com

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