Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of sedative efficacy of ketamine propofol 1 to 3 and fentanyl propofol in cataract surgery by phacoamulsification method

Protocol summary

Study aim
Comparison of the sedative effect of ketamine propofol 1: 3 and fentanyl propofol in cataract surgery by phacoamulsification method

Design
Clinical trials in two community-based and pragmatic groups with blind, randomized 100-person parallel groups

Settings and conduct
The use of two different drugs with specific doses in two groups and comparing their effect on the sedation level in cataract surgery by phacoamulsification in Feyz Hospital in Isfahan. The patient and Researcher unaware of which drugs are used for each patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 90 years undergoing cataract surgery using phacoemulsification methods under local anesthesia and sedation in the first and second classes of the American Anesthetic Association. Exclusion criteria: history of any allergy to the drug used in the design, history of drug addiction, alcohol, benzodiazepine and pregnancy, congestive heart failure, history of head trauma, glaucoma, hypotension, evidence of increased intracranial pressure, psychosis, schizophrenia, active upper respiratory tract infection , Asthma, chronic respiratory disease.

Intervention groups
First intervention group: Combination of ketamine propofol 1: 3 and Second intervention group: combination of fentanyl-propofol to measure sedation levels in comparison with other drugs used in cataract surgery

Main outcome variables
relaxation ; Drug side effects; Average heart rate; Average arterial pressure; Average oxygen saturation; Mean pain severity; Average recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N2**
Registration date: **2018-07-18, 1397/04/27**
Registration timing: **retrospective**

Last update: **2018-07-18, 1397/04/27**
Update count: **0**

Registration date
2018-07-18, 1397/04/27

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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hamidshetabi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
2017-03-21, 1396/01/01

Actual recruitment end date
2018-03-21, 1397/01/01

Trial completion date
empty

Scientific title

Comparison of sedative efficacy of ketamine propofol 1 to 3 and fentanyl propofol in cataract surgery by phacoamulsification method

Public title
Relaxation of Ketamine Propofol and Fentanyl Propofol in Cataract Surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing cataract surgery by phacoamulsification
Exclusion criteria:
.History of any allergy to anesthetic drugs Congestive Heart Failure Cardiac arrest Glaucoma Hypotension Chronic respiratory disease Psychosis Schizophrenia
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The division of patients into two groups is based on a random number table
Blinding (investigator's opinion)
Double blinded
Blinding description
.The study is double blinded.Patient and researcher are unaware of patient groups and type of medication.The medications are prepared by an anesthetist who is unaware of the grouping of patients and is worn by an aluminum foil and encoded by an anesthetist.Demographic information; Sedation level. The quality of pain relief and hemodynamic variables and complications are collected by a patient who is not aware of the type of drug and patient grouping
Placebo
Not used
Assignment
Parallel
Other design features
.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan Universiti of Medical Sciences
Street address
Feiz Hospital . Modares st
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-12-16, 1396/09/25
Ethics committee reference number
IR.MUI.REC.1396.3.627

Health conditions studied

1

Description of health condition studied
Cataract surgery
ICD-10 code
H43.9
ICD-10 code description
Unspecified disorder of vitreous body

Primary outcomes

1

Description
Sedation level based on ramsay score
Timepoint
Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery
Method of measurement
Ramsay score

Secondary outcomes

1

Description
arterial pressure
Timepoint
Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery
Method of measurement
Pressure gauge

2

Description
Heart rate
Timepoint
Immediately before surgery, every 5 minutes during and

after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Oximetry pulse

3

Description

Surgeon Satisfaction

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Likert questionnaire

4

Description

Percent saturation of oxygen

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Oximetry pulse

Intervention groups

1

Description

Intervention group: first: the combination of Ketamine-propofol.Syringe 2 contains pethidine (0.2 mg / kg) with distilled water at a concentration of 5cc (concentration 10mg / cc). Propofol containing 0.6mg / kg Propofol (5mg / cc) and Propofol 4 (5mg / cc) will be administered. Group 1 (Kp) Firstly, the syringe 2 is injected into the header and then injected into the header 3 of the syringe 3 as a 3 or 4 sedation level of ramsay score. In the course of surgery, if you need a deeper sedation than Syringe 4 in 1cc volumes as the dose of salvage and total dose It is recorded.

Category

Treatment - Drugs

2

Description

Intervention group: second: the combination of fentanyl-propofol. Syringe 1 contains fentanyl 2 mcg / kg, which is added by adding 5 cc water. Syringe 3 contains Propofol 0.6 mg / kg at 5 mg / cc and 4 Propofol, 5 mg / cc concentration. In group 1 (PF), the first syringe 1 is injected into the titre. Then, in each case, the syringe number 3 is injected into the titer of the sedation level of 3 or 4 ramsay. At the same time, if necessary, a deep sedation needing a syringe number 4 in 1 cc volumes is recorded as a dental carriage.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz Hospital

Full name of responsible person

Morteza heidari

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feiz hospital ، modares st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaqayeq haqjou javanmard

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Hizar jarib st - Isfahan University of Medical Sciences and Health Services - Deputy of Research and Technology of the University

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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

Esfahan 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
Hamidreza Shetabi

Position
Assistant 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