

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Determination of the effect of sedation of various doses of ketamine propofol in ratios 1 to 2 and 1 to 4 in cataract surgery by phacoemulsification in Fayz Hospital in Isfahan, 1396 - 1397

Protocol summary

Study aim

Determination of the effect of sedation of various doses of ketamine propofol in ratios 1 to 2 and 1 to 4 in cataract surgery by phacoemulsification

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 phacoemulsification 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: 2 Second intervention group : Combination of ketamine propofol 1: 4

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: **IRCT20180416039326N4**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **retrospective**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

Registration date

2018-10-17, 1397/07/25

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

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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

2019-03-21, 1398/01/01

Scientific title

Determination of the effect of sedation of various doses of ketamine propofol in ratios 1 to 2 and 1 to 4 in cataract surgery by phacoamulsification in Fayz Hospital in Isfahan, 1396 - 1397

Public title

Determination of the effect of sedation of various doses of ketamine propofol in ratios 1 to 2 and 1 to 4 in cataract surgery by phacoamulsification

Purpose

Treatment

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
- Investigator

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

Isfahan

Postal code

8174673461

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.MUI.REC.1396.3.628

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

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

4

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

Intervention groups

1

Description

Intervention group: first: the combination of Ketamine - propofol. Syringe 2 contains pethidine (0.4 mg / kg) with distilled water at a concentration of 5cc (concentration 10mg / cc). Propofol containing 0.8mg / 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 2cc volumes as the dose of salvage and total dose It is recorded.

Category

Treatment - Drugs

2

Description

Intervention group: Second : the combination of Ketamine- propofol. Syringe 2 contains pethidine (0.3 mg / kg) with distilled water at a concentration of 5cc (concentration 10mg / cc). Propofol containing 1.2mg / 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 2cc volumes as the dose of salvage and total dose It is recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz Hospital

Full name of responsible person

Hamidreza Shetabi

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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

Street address

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

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sh_haghjoo@med.mui.ac.ir

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

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Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

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Postal code

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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