

# 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 phacoemulsification method

#### Protocol summary

##### Study aim

Comparison of the sedative effect of ketamine propofol 1: 3 and fentanyl propofol in cataract surgery by phacoemulsification 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 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: 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)

##### Phone

+98 31 3620 2020

##### Email address

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 phacoemulsification 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 phacoemulsification

##### 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

Isfahan

###### 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

**Street address**

feiz hospital , modares st

**City**

isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱۸۱۷۴۶

**Phone**

+98 31 3445 2034

**Email**

M\_Heidari@med.mui.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

shaqayeq haqjou javanmard

**Street address**

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

**City**

isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Phone**

+98 31 3668 5149

**Email**

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

Email

m\_heidari@med.mui.ir

## 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

**Street address**

Feiz Hospital , Modares St

**City**

isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Phone**

+98 31 3668 8138

**Email**

hamidshetabi@med.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Morteza heidari

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Faiz Hospital , Modares St

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Phone**

+98 31 3668 5555

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Feiz Hospital , Modares St

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Phone**

+98 31 3668 8138

**Email**

hamidshetabi@med.mui.ac.ir

## 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