# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jun 2026

## Comparison of the Effects of sublingual fentanyl and intravenous ketamine on pain control and hemodynamic variables in phacoemulsification cataract surgery under sedation and local anesthesia

## Protocol summary

**Study aim**

Determining the effect of sublingual fentanyl in comparison with intravenous ketamine on pain control and hemodynamic parameters during and after cataract surgery by phycoemulsification under local sedation and anesthesia

**Design**

Double-blind randomized clinical trial on 86 patients candidates for cataract surgery in Feyz Hospital, Isfahan, randomization by random allocation software

**Settings and conduct**

place: Feyz Hospital, Isfahan;blinding: double-blind; the patient and the observer who collects the information are unaware of the drug grouping; Method: 86 patients (43 patients in each group) are candidates for cataract surgery in two groups of sublingual fentanyl at a dose of 1.5µ/kg and intravenous ketamine at a dose of 0.3 mg/kg. Propofol will be injected by infusion to induce sedation in both groups

**Participants/Inclusion and exclusion criteria**

Inclusion:Patients aged 50-75 with ASA class 1 and 2 that Candidates for phycoemulsification who are willing to enter the study Exclusion:History of any allergic reaction to any of medications used in the study؛pregnancy؛seizure or psychotic disorder؛preoperative hypotention؛Taking medication preoperatively (other than those mentioned before)؛lesion of the oral cavity that interferes with sublingual administration of the drug؛increase intracranial pressure

**Intervention groups**

In the sublingual fentanyl group (SLF), fentanyl at a dose of 1.5µ/kg (up to 100µg) is administered sublingually to the patient, and in the intravenous ketamine group (IVK), ketamine at a dose of 0/3 mg/kg injected intravenously. To induce sedation in both groups, 15 ml of propofol (1%), which is reduced to 20 cc with 5 cc of 5% dextrose (containing 7.5 mg/ml of propofol) by infusion pump at a rate of 0.4 ml/kg/h to receive propofol at a sedative dose of 50 micrograms per kilogram of body weight per minute

**Main outcome variables**

pain Control and hemodynamic parameters

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180416039326N18**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-08, 1399/12/18**
Update count: **0**

**Registration date**

2021-03-08, 1399/12/18

**Registrant information**

**Name**
Hamidreza Shetabi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3620 2020
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-03-05, 1399/12/15

**Expected recruitment end date**

2021-09-22, 1400/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effects of sublingual fentanyl and intravenous ketamine on pain control and hemodynamic variables in phacoemulsification cataract surgery under sedation and local anesthesia

**Public title**

Comparison of the Effects of sublingual fentanyl and intravenous ketamine in phacoemulsification cataract surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients aged 50-75 with ASA (American Society of Anesthesiology) class 1 and 2 that Candidates for phycoemulsification cataract surgery who are willing to enter the study

**Exclusion criteria:**

History of any allergy or allergic reaction to any of medications used in the study pregnancy seizure or psychotic disorder preoperative hypotention Taking medication preoperatively (other than those mentioned before) Inflammation or any lesion of the oral cavity that interferes with sublingual administration of the drug increase intracranial pressure

**Age**

From **50 years** old to **75 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **86**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the operating room, based on a random allocation software table , one of the compounds of sublingual fentanyl or intrvenous ketamine is given to patients

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient and the researcher are not aware of the type of medication used. Medications are prepared by an anesthetic expert who has no role in the study and then injected by an anesthetist to each patient group. The person who records the data is also unaware of the type of medication used

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committe of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences and Health Services, Building No.4, Research and Technology Deputy of University,Hezar Jarib Street, Isfahan,Iran

**City**

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**Province**

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8174673461

**Approval date**

2020-05-02, 1399/02/13

**Ethics committee reference number**

IR.MUI.MED.REC.1399.103

## Health conditions studied

### 1

**Description of health condition studied**

cataract surgery

**ICD-10 code**

H26.9

**ICD-10 code description**

Unspecified cataract

## Primary outcomes

### 1

**Description**

Sedation level based on ramsay score

**Timepoint**

every 5 minutes during surgery and then in recovery every 15 minutes, until discharge from recovery

**Method of measurement**

Ramsay score

## Secondary outcomes

**1**

**Description**
Arterial blood pressure
**Timepoint**
Before surgery, during surgery every 5 minutes and in recovery every 15 minutes, until discharge from recovery
**Method of measurement**
pressure gauge

**2**

**Description**
oxygen saturation
**Timepoint**
Before surgery, during surgery every 5 minutes and in recovery every 15 minutes, until discharge from recovery
**Method of measurement**
Pulse oximeter

**3**

**Description**
Heart rate
**Timepoint**
Before surgery, during surgery every 5 minutes and in recovery every 15 minutes, until discharge from recovery
**Method of measurement**
Pulse oximeter

**4**

**Description**
Intensity of pain
**Timepoint**
in recovery every 15 minutes, until discharge from recovery
**Method of measurement**
Universal Pain assessment tool

**5**

**Description**
recovery time
**Timepoint**
After surgery until the discharge from the recovery
**Method of measurement**
Minute Numbers

**6**

**Description**
Patient satisfaction
**Timepoint**
At the time of discharge from recovery
**Method of measurement**
Likert questionnaire

**7**

**Description**
Surgeon satisfaction
**Timepoint**
after surgery
**Method of measurement**
Likert questionnaire

**8**

**Description**
Adverse drug reaction
**Timepoint**
During surgery and in recovery
**Method of measurement**
Adverse drug reaction questionnaire

## Intervention groups

**1**

**Description**
Intervention group: In the sublingual fentanyl (SLF) group, fentanyl at a dose of 1.5µ / kg (up to 100 micrograms), which is reduced to 2 ml with normal saline, is administered sublingually to the patient. first 2 cc fentanyl (up to 100 micrograms) is administered sublingually. After 10 minutes, we ask patients to remove the contents of their mouth and then 2 cc of normal saline is injected intravenously. To induce sedation propofol (1%) 15 ml, which is reduced to 20 cc with 5 cc of 5% dextrose (containing propofol 7.5 mg / ml) by infusion with a pump at a rate of 0.4 ml per Weight per hour to receive propofol at a sedative dose of 50 micrograms per kilogram of body weight per minute. If further sedation is required, a rescue dose of 2 cc propofol at a concentration of 5 mg / cc will be given as a bolus.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: In intravenous ketamine (IVK) group, first 2 cc of normal saline is administered sublingually. After 10 minutes, we ask patients to remove the contents of their mouth and then ketamine at a dose of 0.3 mg / kg which is reduced to 2 ml with normal saline is injected intravenously. To induce sedation propofol (1%) 15 ml, which is reduced to 20 cc with 5 cc of 5% dextrose (containing propofol 7.5 mg / ml) by infusion with a pump at a rate of 0.4 ml per Weight per hour to receive propofol at a sedative dose of 50 micrograms per kilogram of body weight per minute. If further sedation is required, a rescue dose of 2 cc propofol at a concentration of 5 mg / cc will be given as a bolus.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Feyz 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 Haghjooye Javanmard
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Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.
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**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**
Hamidreza Shetabi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for updating data

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## 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**
Unidentifiable individual data can be shared.
**When the data will become available and for how long**
6 months after publication of paper
**To whom data/document is available**
Only available to scholars working in academic and academic institutions
**Under which criteria data/document could be used**
Use for research and treatment purposes
**From where data/document is obtainable**
Email of the person in charge of public accountability: Hamidshetabi@med.mui.ac.ir
**What processes are involved for a request to access data/document**
after request via email, it will be sent if available within a maximum of 1 month.
**Comments**