

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 phacoemulsification 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 1.5 μ /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 phacoemulsification 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 hypotension;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 1.5 μ /kg (up to 100 μ g) 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

Email address

hamidshetabi@med.mui.ac.ir

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 phacoemulsification 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 intravenous 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 committee 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

Isfahan

Province

Isfahan

Postal code

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 1.5 μ / 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

Street address

Isfahan Modarres St. Feyz Hospital

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3445 2031

Email

Hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaqayeq Haghjooye Javanmard

Street address

Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

Sh_haghjoo@med.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

Hamidreza Shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Feyz hospital, Modares St

City

Isfahan

Province

Isfahan

Postal code

81746-73461

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

Hamidreza Shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Feyz hospital, Modarres St

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Fax**Email**

Hamidshetabi@med.mui.ac.ir

Person responsible for updating data**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

Feyz hospital, Modarres St

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3445 2034

Email

Hamidshetabi@med.mui.ac.ir

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