Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the sedative effect of intranasal fentanyl and intranasal ketamine in phacoemulsification cataract surgery under sedation

Protocol summary

Study aim
Determination the sedative effect of intranasal fentanyl and intranasal ketamine in phacoemulsification cataract surgery under sedation

Design
This prospective, randomized, double-blinded clinical trial . The study protocol was approved by the Anesthesiology Department and Ethic Committee of Deputy of Research of Isfahan University of Medical Sciences. Patients aged 30–75 years old scheduled for phacoemulsification cataract surgery under topical anesthesia In Feiz hospital were included in the study.each group contains 40 persons.

Settings and conduct
Randomized double-blind Clinical trial based on random numbers

Participants/Inclusion and exclusion criteria
Inclusion: patients who are candidates for cataract surgery; consent to participate in the study; patients aged 30-75 years old; patients with ASA class 1 and 2. Exclusion: history of allergy or allergic reaction to each of the study drugs; history of head injury; cardiovascular risk; hypertension; severe respiratory disease; advanced liver disease; epilepsy or history of seizure; nervous system disorders; the presence of any tumor or brain metastasis; use of any analgesic and anesthetic drugs; chronic pain syndrome; patients who are not satisfied to enter the study; pregnant women.

Intervention groups
In ketamine group intranasal ketamine 2 ml (1.5 mg/Kg) with maximum dosage of 100 mg administered in both nostrils. In fentanyl group intranasal fentanyl 2 ml (1.5 mcg/Kg) with maximum dosage of 100 mc administered in both nostrils. Both groups received intravenous midazolam 0.04 mg/kg 5 min before surgery. Propofol 2 ml (5mg/ml) as rescue sedative syringe was available to patients in both groups and was administered if the patient was still anxious.

Main outcome variables
Sedation level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170809035601N11**
Registration date: **2019-07-16, 1398/04/25**
Registration timing: **prospective**

Last update: **2019-07-16, 1398/04/25**
Update count: **0**

Registration date
2019-07-16, 1398/04/25

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3668 2105

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparing the sedative effect of intranasal fentanyl and intranasal ketamine in phacoemulsification cataract surgery under sedation

Public title
Comparing the sedative effect of intranasal fentanyl and intranasal ketamine in phacoemulsification

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for Phacoemulsification cataract surgery Patients who are satisfied to enter the study Patients aged 30-75 years old patients with ASA class 1 and 2

Exclusion criteria:
History of any allergy or allergic reaction to any of medications used in the study History of head injurys High intraocular pressure or intracranial pressure Cardiovascular risk Hypertension Severe respiratory disease Advanced liver disease Epilepsy or history of seizure Nervous system disorders The presence of any tumor or brain metastasis Use of any analgesic and anesthetic drug

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In the operating room, based on a random number table, one of the compounds of intranasal fentanyl or intranasal 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 Isfehan University of Medical Sciences

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

City
Isfehan

Province
Isfehan

Postal code
8174673461

Approval date
2019-06-12, 1398/03/22

Ethics committee reference number
IR.MUI.MED.REC.1398.129

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

Timepoint
After induction of anesthesia, during the procedure every 5 minutes

Method of measurement
Modified ramsay sedation scale (RSS)

Secondary outcomes

1

Description
Mean Atrial Pressure

Timepoint
Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery

Method of measurement
Pressure gauge

2

Description
Oxygen saturation percentage
Timepoint
Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery
Method of measurement
Pulse oximetry

3

Description
Heart rate
Timepoint
Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery
Method of measurement
Pulse oximetry

4

Description
Adverse drug reaction
Timepoint
Before surgery, every 5 minutes during surgery and after the surgery every 10 minutes for 30 minutes in recovery
Method of measurement
Adverse drug reaction questionnaire

5

Description
Recovery time
Timepoint
From the end of the surgery to the time exit Recovery
Method of measurement
Minute

6

Description
Surgeon satisfaction
Timepoint
End of surgery
Method of measurement
Likert scale

Intervention groups

1

Description
Intervention group: ketamine group intranasal ketamine 2 ml (1.5 mg/Kg) with maximum dosage of 100 mg administered in both nostrils
Category
Treatment - Drugs

2

Description
Intervention group: fentanyl group intranasal fentanyl 2 ml (1.5 mcg/Kg) with maximum dosage of 100 mc administered in both nostrils
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faiz Hospital
Full name of responsible person
Hamidreza Shetabi
Street address
Toghchi
City
Isfehan
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Isfehan
Postal code
7346181764
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghyegh Haghjoo Javanmard
Street address
Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.
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Isfahan
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Postal code
8174673461
Phone
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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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza shetabi

Position

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Position

Assisstant profesor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period one year after the publication of results

To whom data/document is available

Only available for scholars working in academic and academic centers

Under which criteria data/document could be used

Use of data is permitted for the purpose of developing research on the use of the drug

From where data/document is obtainable

To the email address of the corresponding author

What processes are involved for a request to access data/document

Within two weeks, the requested information will be provided to the applicant

Comments