

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Comparison of the Effectiveness of Nasal Ketamine vs. Intravenous (IV) Ketamine in anesthesia in Patients with Cataract Surgery

#### Protocol summary

##### Study aim

Comparison of the Effectiveness of Nasal Ketamine vs. Intravenous Ketamine in analgesia in Patients with Cataract Surgery

##### Design

Randomised, superiority, parallel, three-way blind, randomized, on 90 patients. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

##### Settings and conduct

This study was a three-course study conducted at the Feyz Isfahan Medical-Educational Center. The available (easy) sampling method and simple randomization method were used using Random allocation software. The patient surgeon and the person collecting the information were unaware of the patients' drug grouping

##### Participants/Inclusion and exclusion criteria

Candidates for Cataract Surgery in adults Criteria for not entering the study: history of allergy or allergic reaction to any of the medications of diet therapy, head injury, high intraocular or intracranial pressure, high-risk cardiovascular disease, hypertension, severe respiratory disease, liver disease, advanced Epilepsy or history of seizures, neurological disorders, tumors or brain metastases, use of any painkillers and anesthesia precursors, chronic pain syndromes, people who are not satisfied with participating in this study

##### Intervention groups

In Intravenous ketamine group, (1 mg / kg with a volume of 3 cc ketamin) is prescribed intravenously and 3 cc of distilled water in the nose. In the nasal ketamine group, 3 cc of ketamine, 1 mg / kg intranasally, and 3 cc of distilled water are administered intravenously.

##### Main outcome variables

Nasal Ketamin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200605047662N2**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **retrospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

##### Registration date

2020-06-09, 1399/03/20

##### Registrant information

##### Name

Hamed Norouzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3422 2149

##### Email address

hamednorouzi7337@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-12-09, 1397/09/18

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

2017-03-20, 1395/12/30

##### Actual recruitment end date

2019-03-20, 1397/12/29

##### Trial completion date

2019-03-20, 1397/12/29

##### Scientific title

Comparison of the Effectiveness of Nasal Ketamine vs. Intravenous (IV) Ketamine in anesthesia in Patients with Cataract Surgery

**Public title**

Effect of Nasal Ketamine in Patients with Cataract Surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

More than 18 years old ASA 1 or 2 Candidate for Cataract Surgery by Phacoemulsification Method

**Exclusion criteria:**

History of any Allergic Reaction to any of the Treatment Regimens History of head injury, high intraocular or intracranial pressure, high-risk for cardiovascular disease, severe respiratory disease, liver disease, advanced epilepsy or seizure history, neurological disorder, tumor or brain metastasis Use of any Anesthetics in last day Chronic Pain Syndromes

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **90**

Actual sample size reached: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The 45 pieces of paper that were written on it A and the other 45 pieces that were written B (a total of 90 pieces) are folded into a non-transparent bag. Then 30 minute before the operation, one of the pieces were selected randomly by a person who does not know about the details. In case of A patient categorized as the intra-venous Ketamine group, and in case of B, it belongs to the nasal Ketamine group.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Patient, surgeon and data collector

**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., Azadegan street., Hezar-Jarib blvd

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-10-02, 1397/07/10

**Ethics committee reference number**

IR.MUI.MED.REC.1397.032

**Health conditions studied****1****Description of health condition studied**

Cataract

**ICD-10 code**

H25

**ICD-10 code description**

Age-related cataract

**Primary outcomes****1****Description**

Relaxation Level during Surgery

**Timepoint**

After Surgery, In Recovery Room

**Method of measurement**

Ramsay Sedation Scale Questionnaire

**2****Description**

Satisfaction of the Surgeon

**Timepoint**

After Surgery

**Method of measurement**

Visual Analogue Scale Questionnaire

**3****Description**

Satisfaction of the Patient

**Timepoint**

After Surgery

**Method of measurement**

Visual Analogue Scale Questionnaire

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Ketamine (1 mg / kg with a volume of 2 cc) was administered Intravenously

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Normal saline (2 cc) was injected intravenously and ketamine (1 mg / kg 2 cc) intravenously.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Feyz Hospital

##### Full name of responsible person

Hamidreza Shetabi

##### Street address

Isfahan University of medical sciences., Hezar-Jarib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3071

##### Email

Hamednorouzi7337@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Hamidreza Shetabi

##### Street address

Isfahan university of medical sciences., Hezar-Jarib street

##### City

Isfahan

##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3792 3071

#### Email

Hamednorouzi7337@gmail.com

#### 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

Hamed norouzi

##### Position

Medical Intern

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

Isfahan University of medical sciences., Hezar-Jarib street

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Hamed Norozi

##### Position

Medical Intern

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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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