Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the premedication effects of Fentanyl and Ketamine on perioperative hemodynamic stability and postoperative pain in patients undergoing general anesthesia using laryngeal mask for cataract surgery

Protocol summary

Study aim
Comparing the premedication effects of Fentanyl and Ketamine on perioperative hemodynamic stability and postoperative pain in patients undergoing general anesthesia using

Design
A double-blind clinical trial in which patients are randomly divided into two groups, A and B.

Settings and conduct
In this clinical trial patients are not aware of the grouping, the drugs are coded and prepared by the nurse anesthetist and provided to the researcher (who observe and record the research process).This study is performed in Kowsar Hospital in Sanandaj, Kurdistan, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria : patients with cataracts; being at I & II level of ASA Classification; age between 40-70 years; consent to participate in the study Exclusion criteria: confirmed ,suspicious or in treatment Schizophrenia; hydrocephalus brain mass resulting in raised Intracranial pressure; thyroid porphyria; untreated cardiovascular disease; opium abuse during last week before operation, using corticosteroid ; untreated ear disease and vertigo uncontrolled hypertension; acute or chronic lung disease; obesity (BMI>30) and operation time lasting more than one hour.

Intervention groups
Intervention group A: In this group, 0.3 mg / kg of ketamine is prescribed as a premedication for patients. After 3 minutes, 1.5 mg / kg intravenous administration of propropofol will be performed.Intervention group B: In this group, µgr/kg 1.5 fentanyl is prescribed as a premedication for patients. After 3 minutes, 1.5 mg / kg intravenous administration of propropofol will be performed.

Main outcome variables
Mean arterial pressure, heart rate during surgery and postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210214050355N1**
Registration date: **2021-05-25, 1400/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-25, 1400/03/04**
Update count: **0**

Registration date
2021-05-25, 1400/03/04

Registrant information

Name
Mehran Rami

Name of organization / entity

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Iran (Islamic Republic of)

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mehran.rami@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-06-05, 1400/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the premedication effects of Fentanyl and Ketamine on perioperative hemodynamic stability and postoperative pain in patients undergoing general anesthesia using laryngeal mask for cataract surgery

Public title
Evaluating the premedication effects of Fentanyl and Ketamine on perioperative hemodynamic stability and postoperative pain in patients undergoing general anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with cataracts Age 40 to 70 years Being at level 1 and 2 of the ASA system Consent to participate in research

Exclusion criteria:
Uncontrolled Cardiovascular disease Opioids abuse during the weak before operation Patients who are taking corticosteroids Ear disorders and Vertigo Uncontrolled Diabetes Mellitus Uncontrolled Hypertension Acute or chronic Pulmonary diseases Obesity (BMI>30) Probable Schizophrenia; Schizophrenia and in treatment Schizophrenia Brain mass; Hydrocephalus; Raised ICP Porphyria Thyroid malfunction Patients whose operation lasts more than an hour

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample will be assigned to 2 groups at random so that patients with the condition are assigned to the researcher in the form of a double block (AB) by the researcher. Then a pack containing 49 cards with one of the letters A and B (44 each) is considered to randomly select a card from the package and enter one of the groups according to the Latin letter. Sampling is done in parallel in 2 groups until the number of samples is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are not aware of the grouping, also the drugs are coded and prepared by the nurse anesthetist and provided to the researcher (who observe and record the research process).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran St. Kurdistan University of Medical Sciences

City
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2021-01-05, 1399/10/16

Ethics committee reference number
IR.MUK.REC.1399.265

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
Pain

Timepoint
30 and 60 minutes after the end of anesthesia

Method of measurement
Visual analogue scale

2

Description
Mean Arterial Pressure

Timepoint
Induction time of venous anesthesia, After induction and before placement of laryngeal mask, Immediately after laryngeal mask placement, Ten minutes after induction

of anesthesia,20 minutes after induction of anesthesia, Recovery Delivery Time, Recovery Discharge Time

Method of measurement

Barometer of medical monitoring device

3

Description

Harte Rate

Timepoint

Induction time of venous anesthesia, After induction and before placement of laryngeal mask, Immediately after laryngeal mask placement, Ten minutes after induction of anesthesia,20 minutes after induction of anesthesia, Recovery Delivery Time, Recovery Discharge Time

Method of measurement

Medical monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, patients have prescribed 0.3 mg/kg ketamine as a premedication. After 3 minutes, induction of anesthesia with propofol at a dose of 1.5 mg/kg intravenously will be done in one dose. The injection is a single dose and the drug is a product of STEROP company in Belgium.

Category

Treatment - Drugs

2

Description

Second intervention group: In this group, 1.5 fentanyl µgr/kg is prescribed as a premedication for patients. After 3 minutes, induction of anesthesia with propofol at 1.5 mg/kg intravenously will be performed. The injection is a single dose and the drug is a product of STEROP company in Belgium.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Mehran Rami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Mehran Rami

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data on the primary outcomes will be shared.
When the data will become available and for how long
Six months after the publication of the results data access is possible.
To whom data/document is available
Academic Researchers
Under which criteria data/document could be used
Meta-analysis is allowed.
From where data/document is obtainable
Dr. Mehran Rami via email: Mehran.Rami@gmail.com
What processes are involved for a request to access data/document
Three months after the request, the data will be sent.
Comments