Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of perioperative intravenous ketamine with fentanyl in control of acute pain after inguinal hernia repair surgery

Protocol summary

Study aim
Comparison of the effect of perioperative intravenous ketamine with fentanyl in control of acute pain after inguinal hernia repair surgery

Design
A randomized, double-blind clinical trial with a parallel groups design; phase 1-2; on 60 patients; divided into two groups of ketamine and fentanyl (control) by random software allocation.

Settings and conduct
This study will be conducted in urmia Imam Khomeini Medical Center. After entering the study, the participants will be randomly assigned to one of two ketamine and fentanyl (control) groups with 30 participants in each group. The patients and the nurse who will take care of them during the procedure will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 30-60 aged adults with inguinal hernia, Absence of contraindications for ketamine and opioids use, patients with American Society of Anesthesiologist (ASA) physical status I,II Exclusion criteria: History of allergic reactions to the drug under study, History of underlying diseases (diabetes, peptic ulcer, gastritis, coronary artery disease, renal failure), Any known psychiatric disorder, Patients with incarcerated hernia, patients with severe infection

Intervention groups
Intervention group: In ketamine group, Induction of anesthesia is done with 1 to 4 mg/kg of intravenous ketamine, and then in maintenance phase, intravenous perfusion of ketamine at a rate of 2 to 10 µg/kg/min will be prescribed. Control group: In fentanyl group, induction of anesthesia is performed with 1-2 µg/kg fentanyl as a routine anesthetic drug, and then maintenance phase, continuous infusion of fentanyl at a rate of 1-2 µg/kg/hr will be prescribed.

Main outcome variables
Postoperative pain measurement at 60, 90 minutes and 24 hours after surgery with numeric rating (NRS) scale from 0 to 10

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221126056613N5**
Registration date: **2023-08-27, 1402/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-27, 1402/06/05**
Update count: **0**

Registration date
2023-08-27, 1402/06/05

Registrant information

Name
aliakbar nasiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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nasiriali7@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of perioperative intravenous ketamine with fentanyl in control of acute pain after inguinal hernia repair surgery

Public title
Comparison of the effect of ketamine with fentanyl in control of acute pain after surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
30-60 aged adults with inguinal hernia Absence of contraindications for ketamine and opioids use patients with American Society of Anesthesiologist (ASA) physical status I,II
Exclusion criteria:
History of allergic reactions to the drug under study History of underlying diseases (diabetes, peptic ulcer, gastritis, coronary artery disease, renal failure) Any known psychiatric disorder Patients with incarcerated hernia patients with severe infection
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two ketamine and fentanyl (control) groups using Random Allocation computer software. In this way, numbers are given to the patients according to the determined sample volume, and then the software allocates the patients to two ketamine and fentanyl (control) groups based on the given numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
After introducing the study to the patients and explaining the benefits and harms of the possible intervention, written consent is obtained from the patients. Then the patients are randomly assigned to one of the intervention or control groups. Patients and nurses who take care of the patients during the trial are blinded to the intervention and control groups, so that none of the nurses and patients know which drug, ketamine or fentanyl, the patients have been under general anesthesia with.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of urmia University of Medical Sciences
Street address
West Azarbaijan University of Medical Sciences, Resalat Blvd, urmia
City
urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.UMSU.REC.1402.040

Health conditions studied

1

Description of health condition studied
inguinal hernia
ICD-10 code
K40.9
ICD-10 code description
Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
intensity of pain
Timepoint
At 60, 90 minutes and 24 hours after surgery
Method of measurement
Based on numeric rating scale (NRS)

2

Description
The consumption of opioids for pain after surgery
Timepoint
Up to 24 hours after the surgery
Method of measurement
Based on milligrams

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In ketamine group, Induction of anesthesia is done with 1 to 4 mg/kg of intravenous ketamine, and then in maintenance phase, intravenous perfusion of ketamine at a rate of 2 to 10 µg/kg/min will be prescribed.
Category
Treatment - Drugs

2

Description
Control group: In fentanyl group, induction of anesthesia is performed with 1-2 µg/kg fentanyl as a routine anesthetic drug, and then maintenance phase, continuous infusion of fentanyl at a rate of 1-2 µg/kg/hr will be prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini educational and medical center
Full name of responsible person
Ali Akbar Nasiri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
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Research and Technology Vice-Chancellor, West Azarbaijan University of Medical Sciences and Healthcare Services, Emergency Room, Resalat Blvd., Urmia
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Grant name
Urmia University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Oroumia University of Medical Sciences
Full name of responsible person
Ali Akbar Nasir
Position
Associate professor
Latest degree
Subspecialist
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)
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