

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of Ketamine-Paracetamol versus Fentanyl-Paracetamol versus Paracetamol Monotherapy for Acute Postoperative Pain Management Using Patient-Controlled Analgesia in Patients Undergoing Femoral Fracture Fixation

Protocol summary

Study aim

Comparison of the efficacy of ketamine-paracetamol and fentanyl-paracetamol combination regimens versus paracetamol monotherapy in controlling acute postoperative pain using patient-controlled analgesia in patients undergoing femoral fracture fixation

Design

Randomized, double-blind, parallel-group clinical trial
Randomization method: Stratified block randomization based on age and gender, using R software
The final sample size was considered 20 patients per group and a total of 60 patients for the three groups

Settings and conduct

Trained nurses will screen and enroll eligible patients, obtaining written informed consent. An independent observer will perform randomization using sealed envelopes containing codes A, B, and C. The intervention will be administered by the principal investigator or a trained nurse in the recovery room, while a blinded assessor will measure pain (VAS) and sedation (Ramsay Scale) outcomes at designated times.

Participants/Inclusion and exclusion criteria

Patients with ASA physical status class I or II
Aged 20 to 50 years
Patients undergoing femoral fracture surgery
Patients undergoing general anesthesia
Provision of written informed consent by the patient to participate in the study
Absence of acute visual or hearing impairments that would interfere with the patient's ability to understand instructions or use a patient-controlled analgesia pump

Intervention groups

Study groups: three parallel groups (ketamine-paracetamol, fentanyl-paracetamol, paracetamol alone)

Main outcome variables

1-Pain intensity 2-Sedation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250121064471N2**

Registration date: **2026-05-17, 1405/02/27**

Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**

Update count: **0**

Registration date

2026-05-17, 1405/02/27

Registrant information

Name

Mahsa Hajimirza

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-19, 1405/02/29

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	paracetamol, fentanyl-paracetamol) or control (paracetamol) based on this sequence. This method, by concealing the allocation sequence, will prevent bias in the group assignment process. It is expected that other potential confounding variables such as duration of surgery and anesthesia, and body mass index will be balanced between the groups due to the randomization process; this will be confirmed by comparing the baseline characteristics of participants at the start of the study
Scientific title Efficacy of Ketamine-Paracetamol versus Fentanyl-Paracetamol versus Paracetamol Monotherapy for Acute Postoperative Pain Management Using Patient-Controlled Analgesia in Patients Undergoing Femoral Fracture Fixation	Blinding (investigator's opinion) Double blinded
Public title Efficacy of Ketamine-Paracetamol versus Fentanyl-Paracetamol versus Paracetamol Monotherapy for Acute Postoperative Pain Management Using Patient-Controlled Analgesia in Patients Undergoing Femoral Fracture Fixation	Blinding description This study is designed as a double-blind trial. The patients, treating physicians, and evaluating nurses will be unaware of the nature and pharmaceutical composition of the contents of the pain pumps. The pumps used will be completely identical in appearance and will only be identified by coded labels (A, B, and C). The key to these codes will be accessible only to the independent person responsible for preparing the medications and the data supervisor
Purpose Treatment	Placebo Not used
Inclusion/Exclusion criteria Inclusion criteria: Patients with ASA physical status class I or II Aged 20 to 50 years Patients undergoing femoral fracture surgery Patients undergoing general anesthesia Provision of written informed consent by the patient to participate in the study Absence of acute visual or hearing impairments that would interfere with the patient's ability to understand instructions or use a patient-controlled analgesia pump No performance of any sensory-neural block during or after the surgery Exclusion criteria: Substance abuse (opioids), alcohol, or psychotropic drugs Allergy to study medications (ketamine, fentanyl, acetaminophen, etc) Pregnancy or lactation Patient's refusal to continue cooperation in the study Liver dysfunction or elevated liver enzymes History of seizures or psychiatric disorders History of chronic pain or daily analgesic use (more than one week)	Assignment Parallel
Age From 20 years old to 50 years old	Other design features
Gender Both	Secondary Ids empty
Phase 3	Ethics committees <u>1</u>
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor	Ethics committee Name of ethics committee Ethics Committee of Saveh University of Medical Sciences Street address The campus building of Saveh University of Medical Sciences is located at the first exit after the General and Revolutionary Courts building on Namaz Boulevard in Saveh City Saveh Province Markazi Postal code ۳۹۱۹۶۷۶۶۵۱
Sample size Target sample size: 60	Approval date 2026-01-12, 1404/10/22
Randomization (investigator's opinion) Randomized	Ethics committee reference number IR.SAVEHUMS.REC.1404.073
Randomization description Random allocation of patients to the groups will be done using stratified block randomization method. Patients will be stratified into four strata based on two variables: age (under 50 years and 50 years and above) and gender. Then, using R software and the blockrand package, a random allocation sequence with variable blocks will be generated for each stratum and placed in sealed, opaque envelopes. An independent observer will allocate eligible patients to one of three groups: intervention (ketamine-	Health conditions studied <u>1</u> Description of health condition studied Patients undergoing femoral fracture surgery ICD-10 code

S72.9
ICD-10 code description
Unspecified fracture of femur

2

Description of health condition studied
Patients undergoing femoral fracture surgery

ICD-10 code
S72.0

ICD-10 code description
Fracture of head and neck of femur

Primary outcomes

1

Description

1-Pain intensity: The patient's mean pain score will be measured using the Visual Analog Scale (VAS). This scale consists of a 10-centimeter line, with the endpoints labeled from 0 (no pain) to 10 (worst possible pain).

Timepoint

The assessment time points include immediately after surgery and at 2, 6, 12, 18, and 24 hours post-surgery

Method of measurement

This scale consists of a 10-centimeter line, with the endpoints labeled from 0 (no pain) to 10 (worst possible pain).

2

Description

Sedation level: A trained nurse will assess and record the patient's sedation level immediately after surgery and at 2, 6, 12, 18, and 24 hours post-surgery using the Ramsay Sedation Scale (which measures sedation from 1: anxious and agitated or restless, to 6: no response to a painful stimulus) by observing the patient's condition

Timepoint

The assessment time points include immediately after surgery and at 2, 6, 12, 18, and 24 hours post-surgery

Method of measurement

will be assessed and recorded using the Ramsay Sedation Scale (ranging from 1: anxious and agitated to 6: no response to a painful stimulus) by observing the patient's condition

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (fentanyl): In addition to receiving the standard pain control protocol (including paracetamol), this group will also receive fentanyl at a dose of 1 µg/kg. The complete contents of the pump will be prepared in a total volume of 100 mL, and the

infusion rate will be 5 mL per hour, similar to the control group.

Category

Treatment - Drugs

2

Description

: Second intervention group (ketamine): In addition to receiving the standard pain control protocol (including paracetamol), this group will also receive ketamine at a dose of 0.3 mg/kg. The complete contents of the pump will be prepared in a total volume of 100 mL, and the infusion rate will be 5 mL per hour, similar to the control group

Category

Treatment - Drugs

3

Description

This group will receive the standard pain control protocol. The pump contents will include paracetamol at a dose of 10 mg/kg, with the total volume adjusted to 100 mL using normal saline, and will be administered at an infusion rate of 5 mL per hour

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Mahsa Hajimirza

Street address

Shohadaye 17 Shahrivar Hospital, Modarres
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

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Saveh – Namaz Boulevard, after the Building of
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

No

Title of funding source

Saveh 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**

Saveh University of Medical Sciences

Full name of responsible person

Mahsa Hajimirza

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information 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