Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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Recruitment status
recruiting

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

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

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

Purpose
Treatment

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)

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

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-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

Blinding (investigator's opinion)
Double blinded

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

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Approval date
2026-01-12, 1404/10/22

Ethics committee reference number
IR.SAVEHUMS.REC.1404.073

Health conditions studied

1

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?
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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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