Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the Effectiveness of Ketamine vs Morphine Sulfate vs Ketamine-Morphine Sulfate in Intertrochanteric Hip Fracture Pain Management of Patients

Protocol summary

Study aim
Comparing the effectiveness of Ketamine, Morphine sulfate and Ketamine-Morphine sulfate on pain control of intertrochanteric hip fracture patients

Design
clinical trial, 3 intervention groups, double-blind, block randomized, phase 3 on 96 patients, Excel statistical software has been used to randomize patients.

Settings and conduct
With the high prevalence of hip fractures and the increasing trend of the elderly population, it is important to pay attention to the treatment and pain control of these patients. The study will be done in the emergency hospital of Shohada Ashayer Khorramabad. 96 patients are divided into three groups, after random allocation to the groups, they are treated with ketamine, morphine or both at the same time. A group of nurses, according to the pre-designed block sorting method, administers the drugs in 5cc syringes. They will give it to another group of nurses without informing them of the contents for injection. The pain score at the beginning and 30, 60, 90, 120 minutes after taking the drug will be evaluated on a visual analogue scale by an experienced emergency medicine specialist who does not know the type of drug prescribed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 65 years, intertrochanteric hip fracture in pelvic x-ray or CT scan Exclusion criteria: Allergy to Morphine or Ketamine, oxygen saturation less than 90%, change of consciousness

Intervention groups
patients of the first group takes, 0.3 mg/kg of intravenous ketamine and 5 cc of normal saline (placebo) in 5 minutes, second group, 0.1 mg/kg of intravenous morphine and 5 cc of normal saline (placebo) in 5 minutes, and third group 0.15 mg /kg ketamine will be infused simultaneously with 0.1 mg/kg intravenous morphine in 5 minutes.

Main outcome variables
Pain score at the beginning and 30, 60, 90, 120 minutes after taking the medicine on the Visual analogue scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230808059075N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date
2023-08-19, 1402/05/28

Registrant information

Name
Mahdi Arkani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 4230 0652

Email address
maark1375@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-29, 1402/06/07

Expected recruitment end date
2023-10-29, 1402/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Ketamine vs Morphine Sulfate vs Ketamine-Morphine Sulfate in Intertrochanteric Hip Fracture Pain Management of Patients

Public title

Comparison of the Effectiveness of Ketamine vs Morphine Sulfate vs Ketamine-Morphine Sulfate in Intertrochanteric Hip Fracture Pain Management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

There is evidence of femur fracture in the intertrochanteric area in the pelvic x-ray or CT scan of the patient Be over 65 years old

Exclusion criteria:

Patients addicted to opioids Patients with a history of allergy to Morphine or Ketamine Systolic blood pressure greater than 180 or less than 90 mm Hg Arterial oxygen saturation less than 90% Altered state of consciousness Patients who do not cooperate Patients with a history of ischemic heart diseases Patients with a history of kidney diseases Patients with a history of liver diseases Patients with a history of obstructive lung diseases Patients with a history of psychotic diseases People who have taken painkillers before entering the hospital

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning people to the studied groups is by using the block classification method. To control the effect of the confounding variable of gender, these changes are considered as classes and then in each class, people will be assigned to treatment groups using the random block method. In order to eliminate the possibility of final allocation by the person who allocates patients to groups, random block method with unequal volume is used. For this purpose, 3 of the blocks include 6 and some 9 permutations. The unit of randomization is individual and the tool used to randomize the order of entry into the study is Excel statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Before enrolling the patient in the study, the consent form to participate in the research plan will be read to them, and if they agree, the patients will participate in the study. In the injection of drugs, a group of nurses will prepare the prescribed drugs in 5cc syringes according to the pre-designed random block method and will present them to another group of nurses who are responsible for injecting the drugs without informing them of the contents. The pain level of the patients before the drug injection and at 30, 60, 90 and 120 minutes after the end of the drug infusion will be evaluated based on the VAS scale, the responsibility of evaluating the pain score in all patients will be done by an experienced emergency medicine doctor who He does not know the type of drug prescribed, and finally, the difference in the VAS score before drug administration and the determined times after drug administration will be used as a criterion for evaluating the success of drugs in reducing pain.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Ethics Committee in Clinical Research, Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moalem St., Khorramabad, Lorestan

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.LUMS.REC.1402.149

Health conditions studied

1

Description of health condition studied

Intertrochanteric hip fracture

ICD-10 code
S72.14
ICD-10 code description
Intertrochanteric fracture of femur

Primary outcomes

1

Description
Pain score on Visual analogue scale
Timepoint
The pain score of the patients at the beginning of the study and 30, 60, 90, 120 minutes after taking the medicine
Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 0.3 mg/kg of Ketamine (ROTEXMEDICA company) intravenously and 5 cc of intravenous normal saline as a placebo will be infused within 5 minutes.
Category
Treatment - Drugs

2

Description
The second intervention group: 0.1 mg/kg of intravenous Morphine (Darou Pakhsh company) and 5 cc of normal intravenous saline will be infused within 5 minutes as a placebo.
Category
Treatment - Drugs

3

Description
The third intervention group: 0.15 mg/kg of Ketamine (ROTEXMEDICA company) and 0.1 mg/kg of intravenous Morphine (Darou Pakhsh company) will be infused simultaneously within 5 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Ashayer Hospital
Full name of responsible person
Mahdi Arkani
Street address
Shohada Ashayer Hospital, Enghelab St.
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Khorramabad
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6816933132
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Bahram Rasoulian
Street address
Shohada Ashayer Hospital, Enghelab St.
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research@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mahdi Arkani
Position

Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data of study participants can be shared after de-identification and information about the main outcome is accessible.
When the data will become available and for how long
The period of access to the data is from the time of printing the results until 6 months later.
To whom data/document is available
Researchers working in all academic and scientific institutions can access documented data.
Under which criteria data/document could be used
For similar research studies and data analysis, access to the documents will be provided by requesting through the academic email to the email of the research committee of Lorestan University of Medical Sciences within one week.
From where data/document is obtainable
To access the data by academic email, send a request to the Vice President of Research and Technology of Lorestan University of Medical Sciences at the address research@lums.ac.ir and contact number +986633120172 or fax number +986633120173 and it will be available to you within a week. You can also contact the contact number +989166296140 and email Maark1375@gmail.com in the name of Mahdi Arkani regarding the data request.
What processes are involved for a request to access data/document
To access the data by academic email, send a request to the Vice President of Research and Technology of Lorestan University of Medical Sciences at the address research@lums.ac.ir and contact number +986633120172 or fax number +986633120173 and it

will be available to you within a week.

Comments