Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effect of intravenous morphine with intravenous ketorolac in relieving pain in patients with limb fractures referred to the emergency department of Khatam An-bia Hospital in Zahedan in 2022

Protocol summary

Study aim
Comparison of the effect of intravenous ketorolac with intravenous morphine in relieving pain caused by broken limbs in patients referred to the emergency room.

Design
This study is a parallel,triple-blind , phase 3 clinical trial with a total sample size of 80 patients, and for randomization, permutation block using rand function of Excel software is used.

Settings and conduct
The location of this study is the emergency room of the hospital, and patients with broken limbs are injected into one group of intravenous morphine and one group of intravenous gatorulac. It is prescribed for the patient. The patient, the outcome assessor and the data analyst do not know the type of drug and blinding has been done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with upper and lower limb fractures between 15 and 60 years old Exclusion criteria: lack of informed consent to participate in the study, pain intensity less than 4 on the VAS scale

Intervention groups
Control group: Patients with broken limbs are injected with intravenous morphine and the amount of pain reduction is checked Intervention group: Ketorolac is injected intravenously to patients with broken limbs and the amount of pain reduction is checked.

Main outcome variables
Initial pain, degree of pain reduction,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054869N3**
Registration date: **2022-11-18, 1401/08/27**
Registration timing: **prospective**

Last update: **2022-11-18, 1401/08/27**
Update count: **0**

Registration date
2022-11-18, 1401/08/27

Registrant information

Name
ali abdolrazaghnejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3323 2890

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of intravenous morphine with intravenous ketorolac in relieving pain in patients with limb fractures referred to the emergency department of Khatam An-bia Hospital in Zahedan in 2022

Public title
Comparison of the effect of intravenous morphine with intravenous ketorolac in relieving pain in patients with limb fractures referred to the emergency department

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Existence of definitive limb fracture based on radiography and pain intensity based on visual analog scale more than 4

Exclusion criteria:
Lack of informed consent Hemodynamic instability Underlying pulmonary problems, History of taking painkillers or narcotic drugs History of liver or kidney disease Head injury Pregnancy Age below 15 years and above 60 years

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of patients to two groups is done by permuted block stratified randomization method. In this way, first, eligible referring patients are classified according to age (15-30, 31-45 and 46-60) in the order of entry. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this research, the triple-blind method is used. So that the person responsible for recording the results, the patient and the data analyst will not be aware of the intended intervention.Both drugs in the intervention and control groups are injected intravenously for 5 minutes through a covered syringe, and the patient does not know the contents of the syringe.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Daneshgah blvd

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Approval date
2022-10-25, 1401/08/03

Ethics committee reference number
IR.ZAUMS.REC.1401.284

Health conditions studied

1

Description of health condition studied
Pain management in patients with limb fractures

ICD-10 code
G89.11

ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Pain score

Timepoint
Before the intervention and 10, 20, 40, 60, 75 minutes after the intervention

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Respiratory depression

Timepoint
10, 20, 40, 60, 75 minutes after the intervention

Method of measurement
Having or not having a side effect after the intervention

2

Description
Headache

Timepoint
10, 20, 40, 60, 75 minutes after the intervention

Method of measurement
Having or not having a side effect after the intervention

3

Description
Dizziness
Timepoint
10, 20, 40, 60, 75 minutes after the intervention
Method of measurement
Having or not having a side effect after the intervention

4

Description
Drowziness
Timepoint
10, 20, 40, 60, 75 minutes after the intervention
Method of measurement
Having or not having a side effect after the intervention

Intervention groups

1

Description
Intervention group: Intravenous ketorolac 30 mg, 1 cc of Caspian Daru Company, which is administered intravenously to the patient within 5 minutes after the patient enters the study according to the study protocol.
Category
Treatment - Drugs

2

Description
Control group: 5 cc of intravenous morphine of pakhsh daroo company equivalent to 5 mg will be administered intravenously within five minutes after the patient enters the study and according to the study protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam-Al-Anbia hospital
Full name of responsible person
Ali Abdolrazaghnejad
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Sponsors / Funding sources

1

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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Ali Abdolrazaghnejad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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
All data can be shared after de-identifying individuals.
When the data will become available and for how long
Access starts one year after results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The use of documentation for research exploitations in the field of drug therapy is unimpeded only for researchers.
From where data/document is obtainable
Correspondence with the email address ali.abdolrazaghnejad@zaumas.ac.ir.
What processes are involved for a request to access data/document
After sending the applicant's application and receiving the email, if the applicant is eligible, the data files will be sent to the email address.
Comments