

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

Drowsiness

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 paksh 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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Khatam square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

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?

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