Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Comparison between effectiveness of oral potassium diclofenac and intravenous acetaminophen in pain management of patients with acute, isolated and closed limb trauma who comes to emergency ward

Protocol summary

Summary

All patients with isolated closed acute limb traumatic pain with our inclusion criteria randomly assigned to study groups. First group will receive oral potassium diclofenac (50 mg tablet of potassium diclofenac) and second group will receive intravenous acetaminophen(1 gram in 500 cc of normal saline in 20 min). At first pain severity will be checked by VAS (pain score) and also vital sign will be checked in the beginning of the study and 5, 15, 30, 60 min and 4 hours after the drug prescription. demographic criteria, patient satisfaction of pain control and adverse effect of treatment will be record. intravenous fentanyl will be prescribed in patients if pain uncontrolled after 60 min of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703018872N11**
Registration date: **2017-07-17, 1396/04/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tehran University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effectiveness of oral potassium diclofenac and intravenous acetaminophen in pain management of patients with acute, isolated and closed limb trauma who comes to emergency ward

Public title

Evaluation oral potassium diclofenac effectiveness in pain control of patients with isolated and acute limb trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: isolated and closed limb trauma; age>18; pain score> 3(pain score) ;consent to participation in the study. Exclusion Criteria: cardiovascular instability; recent analgesic consumption; drug addiction; intravenous opioid administration by prehospital emergency staff or triage nurse; oral intake intolerance; decreased level of consciousness; dementia; multiple trauma, open limb fractures; language barrier.

Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Qods street, keshavarz Blvd
City
Tehran
Postal code
Approval date
2016-01-18, 1394/10/28
Ethics committee reference number
IR.TUMS.REC.1394.1668

Health conditions studied

1

Description of health condition studied
lower limb trauma
ICD-10 code
s80-s89
ICD-10 code description
s92-0

2

Description of health condition studied
upper limb trauma
ICD-10 code
s50-59
ICD-10 code description
s62-0

3

Description of health condition studied
wrist and hand trauma
ICD-10 code
s60-69
ICD-10 code description
s62-0

4

Description of health condition studied
elbow and shoulder trauma
ICD-10 code
s40-49
ICD-10 code description
s42-0

5

Description of health condition studied
pelvic and thigh trauma
ICD-10 code
s70-79
ICD-10 code description
s72-0

6

Description of health condition studied
foot trauma
ICD-10 code
s90-91
ICD-10 code description
s92-0

Primary outcomes

1

Description
evaluation of pain severity
Timepoint
before intervention and then 5, 15, 30, 60 min and 4 hour after intervention
Method of measurement
VAS

Secondary outcomes

1

Description
patient satisfaction
Timepoint
after completion on intervention
Method of measurement
patient claim

Intervention groups

1

Description
First group will receive oral potassium diclofenac (50 mg tablet of potassium diclofenac) and second group will receive intravenous acetaminophen(1 gram in 500 cc of normal saline in 20 min)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Morteza Saeedi
Street address
North Amirabad street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh Basti
Street address
Building No 1, North entrance door of Tehran University, Poursina sreet, Qods street, Enghelab street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty