

# 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

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#### 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.

#### 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

#### 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

+98 21 8490 2719

#### Email address

#### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Mehdi Momeni

#### Position

Assistant professor/ Emergency Medicine specialist

#### Other areas of specialty/work

#### Street address

Shariati Hospital, North Amirabad street

#### City

Tehran

#### Postal code

1411713135

#### Phone

+98 21 8490 2717

#### Fax

#### Email

mahdi129@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Morteza Saeedi

#### Position

Associate professor/ Emergency Medicine specialist

#### Other areas of specialty/work

#### Street address

Shariati Hospital, North Amirabad street

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

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#### Fax

**Email**  
**Web page address**

## **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*