

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of Ketamine with Morphine in control of pain in patients with limb fracture referring to the hospital

#### Protocol summary

##### Study aim

Comparison of the effect of ketamine with morphine on pain control in patients with limb fractures

##### Design

clinical trial study, parallel groups, double blind, randomised

##### Settings and conduct

After approval the study at Kermanshah University of Medical Sciences, it started at Taleghani Hospital Emergency Department. This study was designed as a double blind clinical trial to compare the effect of Ketamine with Morphine in controlling pain in patients with limb fracture. Patients were randomly divided into two groups based on case profile number. The patients and the analyst were blinded to the two groups and prescribed drugs. In this way, the analyst received the information in two groups of A and B . The patients were not informed what drugs were prescribed and the injection was intravenous in both groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria consist of The patient with trauma to limbs, The patient aged of 18 to 80 years old. Exclusion criteria consist of: Decreased level of consciousness. Addiction to opium, Unstable vital sign

##### Intervention groups

Patients were divided into two intervention groups 1 and 2. The intervention group 1 was treated with morphine produced by the Iranian Daroopaksh Company in a dose of 0.1 mg /kg body weight as intravenously in one dose, and the intervention group 2 was treated with Ketamine produced by Rotex Med, Germany Company in a dose of 0.3 mg /kg body weight as intravenously in one dose.

##### Main outcome variables

pain score base of visual analog score

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180108038276N2**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

#### Registration date

2019-06-17, 1398/03/27

#### Registrant information

##### Name

amir noyani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3336 2186

##### Email address

a.noyani@shmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-12-22, 1397/10/01

#### Expected recruitment end date

2019-07-01, 1398/04/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of Ketamine with Morphine in control of pain in patients with limb fracture referring to the hospital

**Public title**

Ketamine and Morphine role in control of pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patient with limbs trauma patients with aged of 18 to 80 years old

**Exclusion criteria:**

The patient with decreased level of consciousness The patient with unstable vital sign Addiction to opium

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

120 Patients entered into the study were divided into two groups of Morphine and Ketamine recipient. They divided in two groups according the file number. Even number in Ketmine group and odd number in Morphine group were placed.The analyst received data as the group A and group B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients and the analyst were blinded to the two groups and prescribed drugs. In this way, the analyst received the information in two groups of A and B . The patients were not informed what drugs were prescribed and the injection was intravenous in both groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic committee of Kermanshah University of Medical Science

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.Kermashah,iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2019-04-30, 1398/02/10

**Ethics committee reference number**

IR.KUMS.REC.1398.096

**Health conditions studied****1****Description of health condition studied**

Traumatic Patients

**ICD-10 code**

G89.11

**ICD-10 code description**

Acute pain due to trauma

**Primary outcomes****1****Description**

Pain Score of limbs fracture Patients according to Visual Analog Scale

**Timepoint**

before intervention and 5,10,30 min after administration of drug

**Method of measurement**

Visual Analog Scale

**Secondary outcomes****1****Description**

Pain Relief

**Timepoint**

before intervention and in 5-10-30 minutes after intervention

**Method of measurement**

Visual Analogue Scale

**Intervention groups****1****Description**

Intervention group 1 was treated with morphine produced by the Iranian Daroopaksh Company in a dose of 0.1 mg /kg body weight intravenously in one dose.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2 was treated with Ketamine produced by Rotex Med, ,Germany Company in a dose of 0.3 mg /kg body weight intravenously in one dose.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani Hosptall Kermanshah

**Full name of responsible person**

Amir Noyani

**Street address**

Taleghani hospital,Taleghani Street,Kermanshah

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+98 23 3223 8115

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A.NOYANI@SHMU.AC.IR

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

Kermanshah university of Medical Science, Taleghani Street, Kermanshah,Iran

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fnajafi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Amir Noyani

**Position**

Assistance professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

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**Position**

Assistance Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

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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**

Data on demographic information and patient pain are distributed as anonymous codes

**When the data will become available and for how long**

Starting data access is from 2019 .

**To whom data/document is available**

Access to data will be free for anyone interested in research

**Under which criteria data/document could be used**

Granting data for scientific use without fringe is allowed

**From where data/document is obtainable**

Can contact with a.noyani@shmu.ac.ir email

**What processes are involved for a request to access data/document**

About a month from the time of the first call through the email

**Comments**