

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of intravenous morphine with morphine plus low dose of ketamine in trauma patients with severe pain

Protocol summary

Summary

Pain management is one of the most responsibilities of ED physician. Uncontrolled pain has very adverse effects such as patient suffering; sympathetic nerves stimulation and addiction to drugs in future. Aim of this study is finding a way to pain control faster; more efficient and with fewer complications and side effects. This study is a randomized; double blind; multicenters; clinical trial that patient with only trauma to limbs between 18 and 50 years old without head trauma and other diseases except present trauma and without adiction and drug consumptin before beginning of study randomizely divide by two groups. One group receive morphine 0.1 mg /kg +ketamine 0.2 mg/kg in minimum interval of 5 minutes with patient's request and other group receive morphine 0.1 mg/kg +0.02 ml/kg of sterile water as placebo in minimum interval of 5 minutes with patient's request. The major outcomes are pain controls and side effects that evaluate in 0,10,30,60,120 minute of study. The results will analyzed and compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112258104N4**

Registration date: **2012-04-27, 1391/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-27, 1391/02/08

Registrant information

Name

Mohammad Amin Zare

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

ma-zare@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous morphine with morphine plus low dose of ketamine in trauma patients with severe pain

Public title

Pain control in trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients above 18 years old with trauma only to limbs and severe pain (VAS equal or above 6). stable vital signs including systolic blood pressure equal or above 90 mm HG ; pulse rate between 60 and 120 per minute ; O2 saturation equal or above 90%; GCS =15 ; no addiction to drugs ;no consumption opioids or analgesics before begining of study ;no history of leaver diseases ;renal diseases; respiratory diseases ;cardiovascular diseases ; psychiatric diseases,blood

diseases . Exclusion criteria: history of head trauma and contraindications for ketamine or morphine administration ; allergy to morphine or ketamine ; need to regional nerve block ; unable to conception of VAS;no interest to participate in study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Ghods street- Keshavarz blvd- Tehran

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

21513/ 210 /90/5

Health conditions studied

1

Description of health condition studied

trauma

ICD-10 code

XIII

ICD-10 code description

musculoskeletal sysytem and connective tissue diseases

Primary outcomes

1

Description

Pain control

Timepoint

0, 10, 30, 60, 90 and 120 minutes after treatment

Method of measurement

Visual Analogous Scale (VAS)

Secondary outcomes

1

Description

Side effects and changes in vital signs

Timepoint

30 and 60 minutes after treatment

Method of measurement

Patient monitoring

Intervention groups

1

Description

intervention group :administration of morphine 0.1 mg /kg +ketamine 0.2 mg/kg in minimum interval of 5 minutes with patient's request and evaluation of pain score and side effects in minutes 0;10;30;60;90;120 of study.

Category

Treatment - Drugs

2

Description

control group :administration of morphine 0.1 mg/kg +0.02 ml/kg of sterile water as placebo in minimum interval of 5 minutes with patient's request and evaluation of pain score and side effects in minutes 0;10;30;60;90;120 of study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool hospital

Full name of responsible person

Mohamad Amin Zare

Street address

Emergency department, Hazrate Rasool hospital, Niyayesh street, Sattarkhan

City

Tehran

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mohsen Yousefzadeh

Street address

Imam Khomeini St.

City

Tehran

3

Recruitment center

Name of recruitment center

Haft e Tir hospital

Full name of responsible person

Saieed Abbasi

Street address

Shahrre rey, Rejai St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

researching center of Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Tehran University of Medical Sciences

City

Tehran

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

Yes

Title of funding source

researching center of 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

Dr. Mohammad Amin Zare

Position

Assistant Professor

Other areas of specialty/work**Street address**

Satarkhan st., Hazrat Rasool Hospital

City

Tehran

Postal code**Phone**

+98 21 6635 2022

Fax**Email**

mazare@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Saeed Abbasi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Satarkhan st., Hazrat Rasool Hospital

City

Tehran

Postal code**Phone**

+98 21 6635 2022

Fax**Email**

saieedabbasi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohsen Yousefzadeh

Position

MD

Other areas of specialty/work**Street address**

Satarkhan st., Hazrat Rasool Hospital

City

Tehran

Postal code**Phone**

+98 21 4408 8113

Fax**Email**

mohsen.yosefzadeh@yahoo.com

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