Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to severe pain.

Protocol summary

Summary

In this randomized clinical trial, the purpuse is to compare the effect of adding different doses of ketamin to the morphin for analgesia. patients with extremity trauma over 18 years old whom admitted in emergency department for a limb trauma and has moderate and severe pain will be considered. they will be divided into three groups. After injection of 0.1mg / kg of morphine ,low dose of will be add to patients (0.15mg / kg and 0.3mg / kg) in the two groups and several mL of saline as placebo is administered in the third group. Pain on the Visual Analog Scale for Pain-VAS scoring system before and after administration of morphine and ketamine is calculated at regular intervals up to 3 hours. And chart notes will be relevant. Pain relief will be examined and possible complications in three groups. Finally, the effect of ketamine on morphine for pain relief and reduce complications associated with use of this drug will be compared between the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626927N1**
Registration date: **2016-06-09, 1395/03/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-09, 1395/03/20

Registrant information

Name

Mohammad Baghaei

Name of organization / entity

Iran university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice President of Research IN Iran University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to severe pain.

Public title

Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to

severe pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: LIMB TRAUMA;PAIN SCORE>5 ;AGE between 18-65 ; no Underlying disease ; No history of drug allergy ; No history of addiction; Exclusion criteria: Lack of coperation or consent of the patient during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Iran University of Medical Sciences, Research Ethics Committee

Street address

hemmat highway beside the Milad tower Iran University of Medical Sciences

City

tehran

Postal code

Approval date

2015-12-08, 1394/09/17

Ethics committee reference number

ir.iums.rec.1394.9211307032

Health conditions studied

1

Description of health condition studied

UPPER limb injury

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb, level unspecified

2

Description of health condition studied

injuries of upper limb, level unspecified

ICD-10 code

t11

ICD-10 code description

Other injuries of upper limb, level unspecified

3

Description of health condition studied

Other injuries of lower limb, level unspecified

ICD-10 code

t13

ICD-10 code description

Other injuries of lower limb, level unspecified

4

Description of health condition studied

Fracture of lower limb, level unspecified

ICD-10 code

T12

ICD-10 code description

Fracture of lower limb, level unspecified

Primary outcomes

1

Description

pulse rate

Timepoint

At the indicated times after injection: minutes 0 15 30 60 90 120 150 180

Method of measurement

counting

2

Description

respiratory rate

Timepoint

At the indicated times after injection: minutes 0 15 30 60 90 120 150 180

Method of measurement

counting

3

Description

pain

Timepoint

At the indicated times after injection: minutes 0 15 30 60 90 120 150 180

Method of measurement

vissual scale assessment

4

Description
blood pressure
Timepoint
At the indicated times after injection: minutes 0 15 30 60 90 120 150 180
Method of measurement
manometer

5

Description
o2 saturation
Timepoint
At the indicated times after injection: minutes 0 15 30 60 90 120 150 180
Method of measurement
pulse oxymetry

Secondary outcomes

1

Description
nausea
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

2

Description
vomitting
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

3

Description
apnea
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

4

Description
hypoventiation
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

5

Description
aspiration
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

6

Description
confusion
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

7

Description
dysphpria
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

8

Description
drug reaction
Timepoint
To 3 hours after injection.
Method of measurement
patient warning

Intervention groups

1

Description
Injection of 0.1mg / kg of morphine with a few ml of distilled water in separate syringes in the control group
Category
Treatment - Drugs

2

Description
Injection of 0.1mg / kg morphine with low doses of ketamine in the intervention group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye hafte tir hospital
Full name of responsible person
Mohammad Baghaei
Street address
Rajai highway
City
Tehran

2

Recruitment center
Name of recruitment center
Firuzgar hosptal
Full name of responsible person
Mohammad Baghaei
Street address
Firooz alley Valiasr square
City
Tehran

3

Recruitment center
Name of recruitment center
Rasool Akram hospital
Full name of responsible person
Mohammad Baghaei
Street address
Sattarkhan street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President of Research IN Iran University of Medical Sciences
Full name of responsible person
Mrs Irani
Street address
Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice President of Research IN Iran 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

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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