

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of analgesic effects of morphine with the standard dose of 0.1mg / kg and morphine at a dose of 0.05mg / kg with ketamine at a dose of 0.3mg / kg in patients with multiple trauma

Protocol summary

Study aim

Reduction of Morphine use in Patients with Multiple Trauma

Design

Clinical trial, prospective, double-blind, randomized with computer software with a sample size of 70 patients

Settings and conduct

Multiple trauma patients eligible for the study who referred to the emergency department of Al-Zahra and Kashani hospitals in Isfahan were included in the study. And then divided into two groups: 35 patients in the morphine group (0.1 mg / kg, morphine IV is administered for pain control) and 35 patients in the combined group (0.1 mg / kg morphine and mg / kg 0.3 Ketamine IV). Meanwhile, morphine was diluted in the first group to achieve an equal volume of the second group. Before injection, the pain level is asked according to the VAS score (numerical scale 10-0), and after injection, 10, 20 and 30 minutes later, the pain level is asked and, if at these times the pain of the patient according to the VAS score was still above 3, 3mg of additional morphine was injected in both groups, as well as possible side effects were recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:: Multiple trauma patients aged 16-50 years who are alert and have stable vital signs. Exclusion criteria: psychosis, history of cardiovascular disease, penetrating eye trauma, and pulse rate less than 60 beat per minute

Intervention groups

In order to relieve pain in the intervention group, low dose ketamine and low dose morphine are prescribed. The usual dose of morphine and the placebo is administered in the control group.

Main outcome variables

Severity of pain before and after injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N3**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 8804

Email address

drfarhadheydari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effects of morphine with the standard dose of 0.1mg / kg and morphine at a dose of 0.05mg / kg with ketamine at a dose of 0.3mg / kg in patients with multiple trauma

Public title

Reduced Morphine Consumption Using Low Dose Ketamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple trauma patients Alert Stable vital signs

Exclusion criteria:

Psychosis cardiovascular disease open globe injuries severe head trauma RR<60/min

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Both groups were given morphine and then, for blindness in the control group, in addition to the morphine, 5 cc of normal saline is prescribed instead of ketamine. Meanwhile, morphine was diluted in the control group to achieve an equal volume of intervention. Syringes are pre-prepared in binary form and used in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Alzahra hospital, Sofe Ave., Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8177777645

Approval date

2016-07-22, 1395/05/01

Ethics committee reference number

IR.MUI.REC.1395.3.824

Health conditions studied

1

Description of health condition studied

Pain in Multiple Trauma Patients

ICD-10 code

T07

ICD-10 code description

Unspecified multiple injuries

Primary outcomes

1

Description

Pain score

Timepoint

The times are zero (moment of injection) and 10, 20 and 30 minutes

Method of measurement

Visual Analogue Scale(0-10)

2

Description

Side effects

Timepoint

10, 20 and 30 minutes after injection

Method of measurement

Count the number of items registered in the checklist

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before injection, 10, 20 and 30 minutes later

Method of measurement

Manometer(pressure gauge)

2

Description

Heart rate

Timepoint

Before injection, 10, 20 and 30 minutes later

Method of measurement

Count

3**Description**

Respiratory rate

Timepoint

Before injection, 10, 20 and 30 minutes later

Method of measurement

Count

4**Description**

Oxygen saturation level

Timepoint

Before injection, 10, 20 and 30 minutes later

Method of measurement

Pulse oximetry

5**Description**

Patient Satisfaction

Timepoint

30 minutes after injection

Method of measurement

4-level Likert table

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

Intervention group:morphine 0.05mg / kg and ketamine
IV 0.3 mg / kg

Category

Treatment - Drugs

2**Description**

Control group: Morphine 0.1 mg / kg and placebo 5 cc IV

Category

Treatment - Drugs

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

Alzahra and Kashani hospital

Full name of responsible person

Farhad Heydari

Street address

Alzahra Hospital,Sofeh Ave.,Shahid Keshvari Blvd

City

Isfahan

Province

Isfahan

Postal code

8177777645

Phone

+98 31 3620 2020

Email

drfarhadheydari@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Street address

Alzahra Hospital,Sofeh Ave.,Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8177777645

Phone

+98 31 3620 2020

Email

drfarhadheydari@gmail.com

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No 7, Aria Building, Sohrevardi Ave.

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3776 9818

Fax**Email**

drfarhadheydari@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No 7, Aria Building, Sohrevardi Ave.

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3776 9818

Fax**Email**

drfarhadheydari@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No7, Aria Building, Sohrevardi Ave.

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3776 9818

Fax**Email**

drfarhadheydari@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available