

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of analgesic effect of Intravenous sub dissociative ketamine and Intravenous fentanyl in adult patients with acute pain, in Emergency Department, Sina Hospital, 1395 - 1398

Protocol summary

Study aim

Evaluation of analgesic effect of Intravenous sub dissociative ketamine and Intravenous fentanyl in adult patients with acute pain, in Emergency Department

Design

We study on 200 patients that admitted in Emergency Room at Sina Hospital because of any acute pain. Intervention group: Prescribing intravenous Ketamine in dose 0.3 mg per kg and Control group: Prescribing intravenous Fentanyl in dose 1 micro gram per kg. Randomization Windows version 6.0 software. The study is in data collection phase.

Settings and conduct

We study on 200 patients that admitted in Emergency Room at Sina Hospital because of any acute pain. We ask them that score the pain from 1 to 10. If the score is above 5 and there is no exclusion criteria then we explain about our study and give them a consent letter. After their consent he or she takes intravenous Ketamine in 0.3 mg per kg or Fentanyl in 1 microgram per kg. Beforehand we have randomized the patients with Block Stratified Randomization Windows version 6.0 software. In this research the patients do not inform about the medication. And the researcher and the follower are not a same person. We documented the patient's demographic information and vital signs and pain score in the collection sheet. After injection the follower ask her or him about the pain score in minutes 5, 10, 15, 30 and document it. Also the follower check the patient's vital signs in these times and document them and the side effects. We will analyze these data.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Any adult patient (age>18) with acute pain who need analgesia in emergency department and the pain score is above 5/10 Exclusion criteria: Pain score ≤ 5 Pregnancy and post-partum women Altered mental status Allergy to ketamine or fentanyl Body weight ≤ 46

kg or ≥ 115 Unstable vital signs: BP ≤ 90 mmHg or ≥ 180 mmHg , PR ≥ 150 or ≤ 50 bits/min , RR ≤ 10 or ≥ 30 History of recent head or eye trauma History of Siesure History of elevated ICP Chronic pain Renal or hepatic failure Substance or alcohol abuse Documented psychiatric disorders Opium addiction Recent use of narcotic analgesics

Intervention groups

Intervention group: Prescribing intravenous Ketamine in dose 0.3 mg per kg for adult patients in Emergency Room that suffering acute pain and the pain score is above 5/10 Control group: Prescribing intravenous Fentanyl in dose 0.1 macro gram per kg for adult patients in Emergency Room that suffering acute pain and the pain score is above 5/10

Main outcome variables

pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038568N1**

Registration date: **2018-02-15, 1396/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-15, 1396/11/26**

Update count: **0**

Registration date

2018-02-15, 1396/11/26

Registrant information

Name

Ehsanolah Arabpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

ehsan.tums@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effect of Intravenous sub dissociative ketamine and Intravenous fentanyl in adult patients with acute pain, in Emergency Department, Sina Hospital, 1395 - 1398

Public title

Evaluation of analgesic effect of Intravenous Ketamine and Intravenous Fentanyl in adult patients with acute pain, in Emergency Department, Sina Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Any admitted adult patient in Emergency Room He or she has acute and sever pain The pain score is above 5/10

Exclusion criteria:

Pain score ≤ 5 Pregnancy and post-partum women Allergy to ketamine or fentanyl Body weight ≤ 46 kg or ≥ 115 Altered mental status Unstable vital signs: BP ≤ 90 mmHg or ≥ 180 mmHg , PR ≥ 150 or ≤ 50 bits/min , RR ≤ 10 or ≥ 30 History of recent head or eye trauma History of Siesure History of elevated ICP Chronic pain Renal or hepatic failure Substance or alcohol abuse Documented psychiatric disorders Opium addiction Recent use of narcotic analgesics

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

with Block Stratified Randomization Windows version 6.0 software

Blinding (investigator's opinion)

Double blinded

Blinding description

with Block Stratified Randomization Windows version 6.0 software. The patient knows that he or she taking intravenous Ketamine or Fentanyl randomly. The researcher and the person that follows patients are not a same person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Pour Sina Ave, Qods St, Enghelab St

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-06-19, 1396/03/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2665

Health conditions studied

1

Description of health condition studied

Acute pain in Emergency Room

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain score

Timepoint

Minute 0, 5, 10, 15, 30

Method of measurement

Scoring 1 to 10

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prescribing intravenous Ketamine in dose 0.3 mg per kg for adult patients in Emergency Room that suffering acute pain and the pain score is above 5/10

Category

Treatment - Drugs

2

Description

Control group: Prescribing intravenous Fentanyl in dose 1 micro gram per kg for adult patients in Emergency Room that suffering acute pain and the pain score is above 5/10

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Ehsanolah Arabpour

Street address

Hassan Abad Square

City

Tehran

Province

Tehran

Postal code

۱۱۳۶۷۶۹۱۱

Phone

+98 21 6634 8500

Email

hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Qods Ave, Keshavarz Blvd, Central Organization of
Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

tums-research@tums.ac.ir

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

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

Tehran University of Medical Sciences

Full name of responsible person

Pooya Payandemehr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Hassan Abad Square, Sina Hospital, Emergency
Department

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

pooya_mehr@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Pooya Payandemehr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Hassan Abad Square, Sina Hospital, Emergency
Department

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

pooya_mehr@yahoo.com

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Fax**Email**

Ehsan.tums@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Tehran University of Medical Sciences

Full name of responsible person

Ehsanolah Arabpour

Position

Resident Physician

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Sina Hospital, Hasan Abad Square