Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
١١٣٦٧٤٦٩١١
Phone
+98 21 6634 8500
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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 Organozation of Tehran University of Medical Sciences
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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
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Hassan Abad Square, Sina Hospital, Emergency Department
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Latest degree
Specialist
Other areas of specialty/work
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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
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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