

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Efficacy of Fentanyl Versus Subdissociative-dose Ketamine with Haloperidol on Acute Pain in Adult Patients

Protocol summary

Study aim

Comparison of effectiveness and side effects between Fentanyl and Subdissociative-dose Ketamine with haloperidol on Acute Pain

Design

Randomized clinical trial, non inferiority, double blinded, parallel group design of 200 patients. Randomisation computerized with Block Stratified Randomization Windows version 6.0 software

Settings and conduct

In this study adult patients presenting to emergency department of Sina hospital with acute pain will be divided in two groups. First one will be treated by 0/3 mg/kg intravenous Ketamine with 5mg Interavenous Haloperidol. Second group will be treated by 1 µg/kg interavenous Fentanyl. In 5,10,15,30 minutes interval patient's pain will be documented by Verbal Numerical Rating Scale (VNRS) and simultaneously side effects of both groups will be submitted. This study is double blinded .Partients will not be informed about administrated medication . Adminstrating of medications and observing patients situation will be practiced by seperated persons

Participants/Inclusion and exclusion criteria

Any adult patient with acute pain can participate in this research. Patients with mild pain, unstable vital sign, major medical problems or history of substance abuse will be excluded

Intervention groups

First group : patients with acute pain that will be treated with Ketamine and Haloperidol Second group: patients with acute pain that will be treated with Fentanyl

Main outcome variables

Pain relief will be evaluated by Verbal Numerical Rating Scale (VNRS), presence of side effects like agitation by direct observation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047684N1**

Registration date: **2020-07-30, 1399/05/09**

Registration timing: **prospective**

Last update: **2020-07-30, 1399/05/09**

Update count: **0**

Registration date

2020-07-30, 1399/05/09

Registrant information

Name

Mohammad Mobin Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 0317

Email address

m.mobin.moradi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of Fentanyl Versus Subdissociative-dose Ketamine with Haloperidol on Acute Pain in Adult Patients	
Public title	Efficacy of Ketamine on Acute Pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Any adult patient (age>18) with acute pain who need analgesia 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 beats/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	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor
Sample size	Target sample size: 200
Randomization (investigator's opinion)	Randomized
Randomization description	Participants divided in two groups randomly by a statistics specialist with Block Stratified Randomization Windows version 6.0. Each day five participants from those two groups will involved and they will be ordered randomly .Every morning a person not involved in the study or patient care prepared study packages, and stored them in a locked drawer. When each new subject was enrolled by an attending emergency physician, they were allocated to the next number based on the randomizationschedule. The physician then picked up the matched, numbered package from the drawer.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this research participants aren't informed about the adiministrated medication.Due to the similar appearance of the drugs, the syringes are not covered and according to the information given to the patient, distilled water will be injected instead of haloperidol for patients in the control group (fentanyl). Regarding the side effects described to the patient in informed consent, no information was given about the potential for pain relief of the drugs. For blinding, researcher who chooses
	patients to participate in research, person who administrates the medications and observer who observes and documents participant's pain are separated persons.
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 No. 63, Saduqi Ave., Jamalzadeh St City Tehran Province Tehran Postal code ۱۴۱۸۶۱۳۷۴۱ Approval date 2018-11-20, 1397/08/29 Ethics committee reference number IR.TUMS.MEDICINE.REC.1397.930
Health conditions studied	1 Description of health condition studied Acute pain ICD-10 code G89.1 ICD-10 code description Acute pain, not elsewhere classified
Primary outcomes	1 Description Pain score by Verbal Numerical Rating Scale (VNRS) Timepoint 5,10,15 and 30 minutes after administration of medications Method of measurement Verbal Numerical Rating Scale (VNRS) 2 Description Blood pressure

Timepoint

5,10,15 and 30 minutes after administration of medications

Method of measurement

Sphygmomanometer

Secondary outcomes**1****Description**

Agitation scale calculating with Richmond Agitation-Sedation Scale

Timepoint

When agitation appears

Method of measurement

Richmond Agitation-Sedation Scale

2**Description**

Need for rescue analgesic

Timepoint

10 minutes after administration of medications

Method of measurement

Asking from patient about presence of pain

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

Intervention group: patients with acute pain that treated with 0.3 mg/kg intravenous Ketamine and 2.5 mg intravenous Haloperidol. 2.5 mg Haloperidol diluted with distilled water up to 5ml will be injected by 5ml syringe in one minute through IV line .then immediately the calculated dosage of Ketamine will be diluted by distilled water up to 10ml and will be injected by 10ml syringe in two minutes through same IV line.

Category

Treatment - Drugs

2**Description**

Intervention group: patients with acute pain that treated with 1 µg/kg intravenous Fentanyl. In this group first 5ml distilled water will be injected through IV line in one minute insted of Haloperidol then the calculated amount of Fentanyl will be diluted with distilled water up to 10ml and will be injected by 10ml syringe in two minutes through IV line

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Sina hospital

Full name of responsible person

Mohammad Mobin Moradi

Street address

Imam khomeini Ave, Hasan abad Sq.

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 Sahraian

Street address

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8163 3685

Email

vcr@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

Mohammad Mobin Moradi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Emergency Medicine

Street address

No 63, Saduqi Ave, Jamalzadeh St

City

Tehran

Province

Tehran

Postal code

۱۴۱۸۶۱۳۷۴۱

Phone

+98 21 6691 0317

Email

m.mobin.moradi@gmail.com

Full name of responsible person

Mohammad Mobin Moradi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Emergency Medicine

Street address

No 63, Saduqi Ave, Jamalzadeh St

City

Tehran

Province

Tehran

Postal code

۱۴۱۸۶۱۳۷۴۱

Phone

0092166910317

Email

m.mobin.moradi@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Pooya Payandemehr

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Imama khomeini St. Hasan abad Sq

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

pooya_mehr@yahoo.com

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

Tehran University of Medical Sciences

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All collected data will be available

When the data will become available and for how long

6 months after publication

To whom data/document is available

Data will be available for Academic researchers and scientists

Under which criteria data/document could be used

Statistical analysis of data

From where data/document is obtainable

contact M.mobin.moradi@gmail.com

What processes are involved for a request to access data/document

After receiving the application, the requested information will be provided within one month

Comments