Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 wil 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 . Administrating 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
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Iran (Islamic Republic of)
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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 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
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 randomlly .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 interavenous Ketamine and 2.5 mg interavenous 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 interavenous 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
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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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 afer 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