Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of Efficacy of Nebulized Ketamine with Intravenous Morphine in Patients with Multiple Trauma

Protocol summary

Study aim
Comparison of Efficacy of Nebulized Ketamine with Intravenous Morphine in Patients with Multiple Trauma

Design
A randomized controlled clinical trial with parallel, double-blind, randomized groups used a random number table.

Settings and conduct
Obtaining written permission and randomization of patients using a table of random numbers; Age, sex, pain score, complications, need for additional doses of medication and type of injury in both groups at 0, 5, 10, 15, 30 and 60 minutes were recorded in a checklist and finally the data were entered into SPSS program.

Participants/Inclusion and exclusion criteria
Inclusion: Trauma patients with trauma pain with a pain score greater than 4/Age over 4 years/Age less than 65 years Exclusion: Patients with level of consciousness 13/Housing consumption in the last 4 hours/History of seizures/Unsatisfied people to participating in the project/Psychedelics and drug addiction/Maxillofacial trauma in which the patient is unable to use a nebulizer mask/Systolic blood pressure less than 90 and more than 180/Respiratory rate less than 10/pulse rate Less than 60 and more than 140/Suspected of bleeding brain lesions or cerebral edema/Pregnancy/History of allergies to any of the drugs used in the study/Frequent nausea and vomiting/Brain Tumor/Glaucoma

Intervention groups
Intervention:1 mg/kg ketamine nebulizer with a maximum dose of 50 mg, which is brought to a volume of 3 cc with distilled water and poured into the nebulizer chamber, and connected with oxygen lit 5 min/min to 10 lit/min and cc 5 Slowly inject distilled water into a vein. Control:Pour 3 cc of distilled water into the nebulizer and connect with 5 lit/min to 10 lit/min with oxygen and 0.1 mg/kg morphine with a maximum dose of 10 mg diluted with distilled water with a 5 cc syringe inject slowly into the peripheral vein.

Main outcome variables
Severity of pain measured by Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200602047633N1**
Registration date: **2020-11-28, 1399/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-28, 1399/09/08**
Update count: **0**

Registration date
2020-11-28, 1399/09/08

Registrant information

Name
Zahra Rayat Roknabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3237 0718

Email address
zahra.rayat75@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Efficacy of Nebulized Ketamine with Intravenous Morphine in Patients with Multiple Trauma

Public title
Comparison of Efficacy of Nebulized Ketamine with Intravenous Morphine in Patients with Multiple Trauma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Trauma patients with trauma pain with a pain score greater than 4 Age over 4 years Age less than 65 years

Exclusion criteria:
Patients with level of consciousness 13 Housing consumption in the last 4 hours History of seizures Unsatisfied people to participating in the project Psychedelics and drug addiction Maxillofacial trauma in which the patient is unable to use a nebulizer mask Systolic blood pressure less than 90 and more than 180 Respiratory rate less than 10 pulse rate Less than 60 and more than 140 Suspected of bleeding brain lesions or cerebral edema Pregnancy History of allergies to any of the drugs used in the study Frequent nausea and vomiting Brain Tumor Glaucoma

Age
From **15 years** old to **64 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number table Based on a random sequence of numbers from Random.org, a table will be prepared, with the first Hundred consecutive numbers in Group A, the next Hundred consecutive numbers in Group B. These numbers will be assigned to each patient in order of referral.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug is prepared and prescribed by the triage nurse based on which group the patient is in and none of the patients and the evaluating physician will know the type of prescription drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address
Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Sq., Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8916978477

Approval date
2020-05-11, 1399/02/22

Ethics committee reference number
IR.SSU.MEDICINE.REC.1399.023

Health conditions studied

1

Description of health condition studied
Patients with Multiple Trauma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Response to treatment by reducing the pain intensity by two points (20 mm) in terms of visual analog scale (VAS).

Timepoint
Measurement of pain score at the beginning of the study (before the intervention) and 5, 10, 15, 30 and 60 minutes after the start of treatment

Method of measurement
visual analog scale (VAS)

Secondary outcomes

1

Description
Creating analgesia which patient's intensity pain goes below than 5.

Timepoint
Measurement of pain score at the beginning of the study (before the intervention) and 5, 10, 15, 30 and 60 minutes after the start of treatment

Method of measurement
visual analog scale (VAS)

2

Description
Determining the time to start treatment response in two groups
Timepoint
Measurement of pain score at the beginning of the study (before the intervention) and 5, 10, 15, 30 and 60 minutes after the start of treatment
Method of measurement
visual analog scale (VAS)

3

Description
Determining the frequency of patients who failed treatment in two groups
Timepoint
At the end of the study
Method of measurement
Calculate the number

4

Description
Determine the number of times the drug is prescribed
Timepoint
At the end of the study
Method of measurement
Calculate the number

Intervention groups

1

Description
Intervention group:1 mg / kg ketamine nebulizer with a maximum dose of 50 mg, which is brought to a volume of 3 cc with distilled water and poured into the nebulizer chamber, and connected with oxygen lit 5 min / min to 10 lit / min and cc 5 Slowly inject distilled water into a vein.
Category
Treatment - Drugs

2

Description
Control group:Pour 3 cc of distilled water into the nebulizer and connect with 5 liters / min to 10 lit / min with oxygen and 0.1 mg / kg morphine with a maximum dose of 10 mg diluted with distilled water with a 5 cc syringe We inject the face slowly into the peripheral vein.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Dr. Soheila Azimi
Street address
Shahid Ghandi Blvd, Ebne Sina Blvd
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Yazd
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Yazd
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8916886938
Phone
+98 35 3822 4000
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Sadoughi_Hospital@ssu.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Rahnemoun Hospital
Full name of responsible person
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Street address
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Phone
+98 35 3626 0001
Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Yazd, Bahonar Square, the central building of Shahid Sadoughi University of Medical Sciences, Yazd
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8916978477
Phone
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Email
info@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Zahra Rayat Roknabadi
Position
Medical Student
Latest degree
A Level or less
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Person responsible for updating data

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zahra.rayat75@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