Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparison of Intranasal Ketamine Spray and Intravenous Morphine in Reducing Headache in Patients with Headache; A Randomized Double-Blinded Clinical Trial

Protocol summary

Study aim
Comparison of Intranasal Ketamine Spray and Intravenous Morphine in Reducing Headache in Patients with Headache

Design
A randomized controlled clinical trial with parallel, double-blind, phase 2 on 100 patients, randomized groups used a random number table.

Settings and conduct
This double-blind (Researcher and patient) clinical trial was conducted on patients with acute headache referred to emergency departments of Shahid Sadougi and Rahnamon Hospitals in Yazd. Based on random number table, the patients were divided into case groups and control group. Then variables in two groups were measured and recorded; Finally, the data was analyzed using the SPSS software.

Participants/Inclusion and exclusion criteria
The inclusion criteria: older than 14 years and younger than 65 years, pain score greater than or equal to four. The exclude criteria: GCS less than 15, symptoms of increased ICP, symptoms of nerve lateralization, O2 saturation less than 90%, suspected of subarachnoid hemorrhage (SAH), fever and Neck stiffness, history of psychosis, known liver and kidney disease, taking painkillers in the last 4 hours, eye complications, pregnancy and breastfeeding, nasal congestion, drug addiction, systolic blood pressure less than 90 and more than 180, respiratory rate less than 10, pulse rate less than 60 and more than 140, history of allergy to any of the drugs used in the study, brain tumor and not consenting to participate in the project

Intervention groups
50 patients who were treated with intranasal ketamine at a dose of 0.7 mg/kg (the maximum dose was considered 40 mg) in the form of three puffs inside each nostril (each puff containing 7 mg of ketamine) and 10 cc of normal intravenous saline were injected slowly.

Main outcome variables
Severity of pain measured by Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200602047633N2**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **retrospective**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date
2023-08-16, 1402/05/25

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
2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Intranasal Ketamine Spray and Intravenous Morphine in Reducing Headache in Patients with Headache; A Randomized Double-Blinded Clinical Trial

Public title
Comparison of Intranasal Ketamine Spray and Intravenous Morphine in Reducing Headache in Patients with Headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Trauma patients with trauma pain with a pain score greater than 4 Age over 14 years Age less than 65 years
Exclusion criteria:
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **110**
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
2021-09-15, 1400/06/24
Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.188

Health conditions studied

1

Description of health condition studied
Patients with Headache
ICD-10 code
G44
ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
The time to start responding to treatment
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
The rate of complications in both groups
Timepoint
At the end of the study
Method of measurement
Calculate the number

Intervention groups

1

Description
Intervention group: 50 patients who were treated with intranasal ketamine at a dose of 0.7 mg/kg (the maximum dose was considered 40 mg) in the form of three puffs inside each nostril (each puff containing 7 mg of ketamine) and 10 cc of normal intravenous saline were injected slowly.
Category
Treatment - Drugs

2

Description
Control group: 50 patients were treated with placebo nasal spray and 0.1 mg/kg intravenous morphine (the maximum dose was considered 5 mg) were injected slowly which was diluted with 10 cc of normal intravenous saline.
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
Ebne Sina Blvd, Shahid Ghandi Blvd
City
Yazd
Province
Yazd
Postal code
8916886938
Phone
+98 35 3822 4000
Email
Sadoughi_Hospital@ssu.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Rahnemoun Hospital
Full name of responsible person
Dr. Soheila Azimi
Street address
Emergency Alley, Farrokhi St.
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Yazd
Postal code
8913893111
Phone
+98 35 3626 0001
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Rahnemoonhospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
the central building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd
City
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Postal code
8916978477
Phone
+98 35 3724 0171
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
Dr.Soheila Azimi
Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

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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