

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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.

City

Yazd

Province

Yazd

Postal code

8913893111

Phone

+98 35 3626 0001

Email

Rahneemohospital@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

Yazd

Province

Yazd

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

Street address

Ebne Sina Blvd

City

Yazd

Province

Yazd

Postal code

8913893111

Phone

+98 35 3828 2682

Fax

Email

soheila.azimi1987@gmail.com

Person responsible for scientific 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

Street address

Ebne Sina Blvd

City

Yazd

Province

Yazd

Postal code

8913893111

Phone

+98 35 3828 2682

Fax

Email

soheila.azimi1987@gmail.com

Person responsible for updating data

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

Street address

Ebne Sina Blvd

City

Yazd

Province

Yazd

Postal code

8913893111

Phone

+98 35 3828 2682

Fax

Email

soheila.azimi1987@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