Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study on the Effect of Intranasal Ketamine with Intravenous Ketorolac on Reduction of Non-Traumatic Acute headache

Protocol summary

Study aim

Comparison of the efficacy of intranasal ketamine with intravenous ketorolac in reducing non-traumatic acute headache

Design

This study is a randomized controlled clinical trial study and is a double blind study

Settings and conduct

After approval the study at Kermanshah University of Medical Sciences, it started at Taleghani Hospital Emergency Department.Randomization was performed in this study by simple random method. After identifying eligible patients, they will be assigned a random three-digit proprietary code. The last digit on the right determines the patient group. If the figure is 0, 1, 2, 3, 4, it will be placed in the intervention group (Kotorlac) and if the figure is 5, 6, 7, 8, 9 it will be placed in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria consist of :All patients with complaints of non-traumatic acute headache patients with aged of 18 to 50 years old Patients with a variety of headaches including tension and cluster migraine headaches Exclusion criteria consist of: Subjects who have contraindications to the use of ketorolac and vitamin drugs Patients with focal neurological disorder Pregnant and weaning women Patients with headache with impaired consciousness level Patients with Comorbidity Headaches (Liver and Kidney Failure Immune Deficiency)

Intervention groups

In this study, placebo was used for control group. Normal saline was given as placebo in both intranasal and intranasal forms. Given that ketorlac was used intranasally and ketamine injectable, everyone in the intervention group received intranasal ketorlac and normal saline (as placebo). Patients in control group received intranasal ketamine and normal saline (as placebo).

Main outcome variables

pain score base of visual analog score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038276N3**
Registration date: **2019-09-29, 1398/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-29, 1398/07/07**
Update count: **0**

Registration date

2019-09-29, 1398/07/07

Registrant information

Name

amir noyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 2186

Email address

a.noyani@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Comparative Study on the Effect of Intranasal Ketamine with Intravenous Ketorolac on Reduction of Non-Traumatic Acute headache

Public title
Comparison of intranasal ketamine and intravenous ketorolac in reducing non-traumatic acute headache

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with complaints of non-traumatic acute headache patients with aged of 18 to 50 years old Patients with a variety of headaches including tension and cluster migraine headaches

Exclusion criteria:
Subjects who have contraindications to the use of ketorolac and vitamin drugs Patients with focal neurological disorder Pregnant and weaning women Patients with headache with impaired consciousness level Patients with Comorbidity Headaches (Liver and Kidney Failure and Immune Deficiency)

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by simple random method, after identifying eligible patients, they will be randomly assigned a three-digit proprietary code. The last digit on the right determines the patient group. If the figure is 0, 1, 2, 3, 4, it will be placed in the intervention group (Kotorlac) and if the figure is 5, 6, 7, 8, 9, it will be placed in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Nurses and people in charge of care are not aware of the allocation of groups. The person evaluating the patients is also not aware of the allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Kermanshah University of Medical Science

Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.Kermashah,iran

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2019-04-28, 1398/02/08

Ethics committee reference number
IR.KUMS.REC.1398.068

Health conditions studied

1

Description of health condition studied
Patients with acute non-traumatic headaches

ICD-10 code
G44

ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Pain score of patients with acute non-traumatic headache with visual analogue scale

Timepoint
Pain will be measured immediately before drug administration, 30 minutes, 1 minute and 2 hours after drug administration.

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 was treated with intravenous ketorolac at a dose of 0.5 mg / kg intravenously in a single dose.

Category
Treatment - Drugs

2

Description
Intervention group 2 received intravenous ketamine at a dose of 0.5 mg / kg intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital Kermanshah
Full name of responsible person
hooman rafiee sarvari
Street address
Taleghani Hospital,Taleghani Street,Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Kermanshah university of Medical Science, Taleghani Street, Kermanshah,Iran
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
hamid reza beyg rezaee
Position
Assistance professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Title and more details about the data/document
Data on demographic information and patient pain are distributed as anonymous codes

When the data will become available and for how long
Starting data access is from 2019

To whom data/document is available
Access to data will be free for anyone interested in research

Under which criteria data/document could be used
Granting data for scientific use without fringe is allowed

From where data/document is obtainable
Can contact with a.noyani@shmu.ac.ir email

What processes are involved for a request to access data/document
About a month from the time of the first call through the email

Comments