

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 (Ketorolac) 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 ketorolac was used intranasally and ketamine injectable, everyone in the intervention group received intranasal ketorolac 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 (Ketorolac) 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. Kermanshah, 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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6715847167

Phone

+98 23 3223 8115

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hooman.rafiee@yahoo.com

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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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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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