Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparison the Effect of Intravenous Ketamine with Standard Treatment in Migraine Patients Admitted to Emergency Department

Protocol summary

Study aim

to compare the analgesic effect of intravenous (IV) ketamine with standard migraine treatment in patients admitted to emergency department of Shahid Mohammadi Hospital in Bandar Abbas

Design

This evaluation is a phase 3 clinical trial with a control group with parallel, not blinded and not randomized groups, accordingly, 23 people will be evaluated in each group.

Settings and conduct

After receiving the ethics code from the ethics committee of Hormozgan University of Medical Sciences, the study and its risk and potential complications will be explained for patients after obtaining written consent. Primary ECG will be obtained from all patients, all patients will be under cardiac monitoring and female patients will be evaluated for pregnancy. All patients with a history of heart problems, pregnant women and who will not complete written consent form and not meet the inclusion criteria will be excluded from the study. The allocation of patients in two groups will be based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients will be divided into two equal groups of patients, as intervention and control group.

Participants/Inclusion and exclusion criteria

people between 18-70 years' old who referred to emergency department of Shahid Mohammadi Hospital in 2019 with migraine pain

Intervention groups

A group of patients (standard treatment) will receive first-line treatment including 30 mg IV Ketolol and 10mg IV metoclopramide. The other group will receive IV ketamine 1mg/kg in addition to standard treatment. The prescribed drug will be diluted with 10 ml distilled water for 3 to 5 minutes.

Main outcome variables

Headache intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170224032753N2**
Registration date: **2020-03-22, 1399/01/03**
Registration timing: **retrospective**

Last update: **2020-03-22, 1399/01/03**
Update count: **0**

Registration date

2020-03-22, 1399/01/03

Registrant information

Name

Mohammadjavad Khorasani

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 3335 4055

Email address

khorasani@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2019-11-20, 1398/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the Effect of Intravenous Ketamine with Standard Treatment in Migraine Patients Admitted to Emergency Department

Public title
"Comparison the Effect of Intravenous Ketamine with Standard Treatment in Migraine Patients"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Known migraine patients ,referring to emergency department of Shahid Mohammadi hospital in Bandarabbas Age between 18 _ 70 years

Exclusion criteria:
history of cardiac disease not complete the written consent oxygen saturation level below 92 percent systolic blood pressure below 90 or over 180 mmHg heart rate below 50 or higher than 120 beat per minute respiratory rate below 10 or higher than 30 per minute consuming any analgesic 4 hour prior to study pregnancy or lactation liver cirrhosis history of drug reaction with morphine or ketamine or other drugs used in the study patients who are on dialysis weight under 45 or more than 115 kg presence of brain mass, chronic pulmonary disease , history of psychosis , or brain damage

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran National Comittee for Ethics in Biomedical Research

Street address
International Affairs and Scientific Collaborations, Vice-Chancellery for Education of Hormozgan University of Medical Sciences (HUMS),Jomhuri Eslami Blvd, Bandar Abbas, Iran

City
Bandarabbas

Province
Hormozgan

Postal code
7919915519

Approval date
2019-05-19, 1398/02/29

Ethics committee reference number
IR.HUMS.REC.1398.037

Health conditions studied

1

Description of health condition studied
Migraine headache

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache intensity

Timepoint
Before treatment, 30 , 60 and 90 minutes after treatment

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive IV ketamine 1mg/kg in addition to standard treatment including 30mg IV Ketorolac and 10mg IV metoclopramide, The designated drug was diluted with 10 ml distilled water for 3 to 5 minutes.

Category
Treatment - Drugs

2

Description
Control group: received first-line standard treatment including 30mg IV Ketolol and 10mg IV metoclopramide.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Mohammad Javad Khorasani
Street address
Shahid Mohammadi hospital , jomhoori eslami Blvd.
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khorasani@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teimoor Aghamollai
Street address
Vice Chancellery for Research, Payambarazam Hospital , Jomhoorieslami Blvd.
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Bandarabbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Javad Khorasani
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

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
To protect the secrets of patients participating in the project
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available