Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness and side effects of ketamine and haloperidol in controlling acute delirium and acute agitation

Protocol summary

Study aim

Comparison of the effectiveness and side effects of ketamine vs haloperidol for acute control of agitation

Design

This is a phase-3 clinical trial study, two arms parallel group randomized with blinded post-treatment and outcome assessment.

Settings and conduct

This study will be conducted on all patients over 18 years with acute agitation who refer to the emergency department of Qaem, Imam Reza, and Hashemi Nezad hospitals in Mashhad. Herein, patients are divided into two groups based on a table of random numbers, and the name of the prescribed drug is placed inside an envelope in a package. The colleague nurse opens the envelope, prescribes the drug, and then writes the number of the envelope on a checklist which is later completed by the emergency medicine assistant. Then the medical assistant will evaluate the patient and at the end, the envelopes are opened and the prescribed drug for each patient is determined and the data is analyzed. The researcher and medical assistant are blinded in this study.

Participants/Inclusion and exclusion criteria

All agitated patients, after being evaluated for treatable causes such as hypoxia and hypoglycemia are enrolled in this study. Patients with a history of sensitivity to these drugs, any past medical history of dissection or cardiac infarction and QT prolongation, are excluded from the study.

Intervention groups

In this study all patients with acute agitation which is not related to treatable causes are enrolled.

Main outcome variables

1- Determine and compare the side effects of two drugs 2- Determine and compare the time required until the patient's sedation after receiving ketamine and haloperidol 3- Determine and compare the effectiveness of ketamine and haloperidol in controlling patient agitation based on Richmond Agitation Sedation Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058465N1**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

Islamic Republic of Iran Vafadar moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5312

Email address

vafadarme@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-28, 1402/04/07

Expected recruitment end date

2024-06-27, 1403/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness and side effects of ketamine and haloperidol in controlling acute delirium and acute agitation

Public title
Ketamine effectiveness for acute agitation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All acutely agitated patients enrolled in the study. Treatable causes such as hypoxia and hypoglycemia were evaluated in if present, treated.
Exclusion criteria:
Any sensitivity to ketamine or haloperidol, past medical history of dissection or myocardial infarction, or QT prolongation lead to exclude from the study.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **120**
More than 1 sample in each individual
Number of samples in each individual: **60**
Sixty
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups based on a table of random numbers, and the name of the prescribed drug is placed inside an envelope in a package. The colleague nurse opens the envelope, prescribes the drug, and then writes the number of the envelope on a checklist which is later completed by the emergency medicine assistant. Then the medical assistant will evaluate the patient and at the end, the envelopes are opened and the prescribed drug for each patient is determined and the data is analyzed. The researcher and medical assistant are blinded in this study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researcher and the assessor, who is an emergency medicine assistant, are blinded to the drug prescribed by the nurse colleague in the study. At first, based on the table of random numbers, the number and type of prescribed drug is placed in an envelope, the colleague nurse administer the drug without the researcher's accompaniment and records the number of the envelope in the checklist, then the medical assistant evaluated the patient. Finally, after the end of the study, the envelopes are opened and the prescription drug in each checklist is determined and the data are analyzed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic committee of Imam Reza Hospital, Research and Treatment center-Mashhad University of
Street address
Razi squ.
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۳۷۹۱۳۳۱۶
Approval date
2023-05-01, 1402/02/11
Ethics committee reference number
IR.MUMS.IRH.REC.1402.062

Health conditions studied

1

Description of health condition studied
Acute agitation
ICD-10 code
agitation
ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Agitation control based on RASS score
Timepoint
After admission, 30 and 60 minutes after the drug administration
Method of measurement
Agitation control will be assess by Richmond Agitation and Sedation Score.

Secondary outcomes

1

Description
The sedation time based on minutes, the side effects of drugs include apnea, nausea and vomiting, need for intubation, tachycardia, hypertension, tachycardia, QT prolongation, tachycardia, and dysrhythmias.

Timepoint
At admission and 30 and 60 minutes after drug administration

Method of measurement
Any side effects and time to sedation(minutes) will document.

Intervention groups

1

Description
Intervention group: Ketamine Group

Category
Treatment - Drugs

2

Description
Intervention group: Haloperidol group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital, Emam Reza hospital, Shahid Hasheminejad hospital

Full name of responsible person
Ala Montazeri

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Ahmad abad blov., Razi Squ., Abureihan blov.

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https://emamreza.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayour moborhan

Street address
Daneshgah Street, next to Hoizeh Cinema, University of Medical Sciences, 3rd floor, University Research and Technology Vice-Chancellor

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vcresraech@mums.ac.ir

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https://v-research.mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Elnaz Vafadar Moradi

Position
Assistant 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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Mashhad University of Medical Sciences
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Ala Montazeri
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Latest degree
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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
All data can be shared after the completion of the study and after the approval of the ethics committee of the university.
When the data will become available and for how long
immediately after acceptance of the manuscript.
To whom data/document is available
All researchers of academic centers.
Under which criteria data/document could be used
For further investigation
From where data/document is obtainable
Elnaz Vafadar Moradi MD.
What processes are involved for a request to access data/document
You can E-mail me and tell me the reason for requesting the data, I will send to request to ethics committee, and if they approved, I will send the data.
Comments