

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of low-dose intravenous ketamine with haloperidol in reducing delirium and agitation in elderly patients admitted to the intensive care unit: an open-label randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of low-dose intravenous ketamine with haloperidol in reducing delirium and agitation in elderly patients admitted to the intensive care unit: a randomized clinical trial

Design

Non-blind clinical trial on 44 elderly patients admitted to the intensive care unit of hospitals affiliated to Tehran University of Medical Sciences

Settings and conduct

First, individuals were selected using simple randomization and then eligible individuals were selected by random blocking method with a ratio of 1: 1 to two groups, including: groups receiving haloperidol 2.5 mg intramuscularly and receiving ketamine at a dose of 20 mg. Intravenously). At 5, 10, 15 times, the information was completed. In 60 minutes, a checklist of side effects and physician satisfaction is completed.

Participants/Inclusion and exclusion criteria

Age over 65 years and hospitalization in the intensive care unit; Richmond Agitation Sedation Score more equal to 2; not positive troponin and BNP; systolic pressure less than 140 mm Hg; diastolic pressure less than 95; heart rate less than 100

Intervention groups

Group A (receiving ketamine at a dose of 20 mg Intravenously) and group B (receiving haloperidol 2.5 mg intramuscularly)

Main outcome variables

Reynolds and Richmond Score

General information

Reason for update

Changing the blinding process

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058252N1**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **retrospective**

Last update: **2023-07-16, 1402/04/25**

Update count: **1**

Registration date

2023-05-27, 1402/03/06

Registrant information

Name

Seyed Khalil Pestehei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1560

Email address

khalilpesteh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

2021-03-05, 1399/12/15

Actual recruitment end date

2022-03-06, 1400/12/15

Trial completion date

2022-03-21, 1401/01/01

Scientific title

Comparison of the effect of low-dose intravenous

ketamine with haloperidol in reducing delirium and agitation in elderly patients admitted to the intensive care unit: an open-label randomized clinical trial

Public title

Low-dose intravenous ketamine with haloperidol in reducing delirium and agitation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 65 years and hospitalization in the intensive care unit Richmond Agitation Sedation Score more equal to 2 Troponin and BNP not positive Systolic pressure less than 140 mm Hg Diastolic pressure less than 95 Heart rate less than 100

Exclusion criteria:

Dissatisfaction of the patient or the patient's guardian Cardiovascular disease History of psychosis

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

First, individuals were selected using simple randomization and then eligible individuals were selected by random blocking method with a ratio of 1: 1 to two groups. Randomization was performed using random number tables, and the results were assessed by a doctor who was blinded to the study protocol.

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

Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran

Street address

Tehran, end of Keshavarz Boulevard, Imam Khomeini

Hospital

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.548

Health conditions studied

1

Description of health condition studied

Delirium in elderly patients

ICD-10 code

F05

ICD-10 code description

Delirium, not induced by alcohol and other psychoactive substances

2

Description of health condition studied

Agitation in elderly patients

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Reynolds and Richmond score less than one

Timepoint

At the beginning of the study (before the injection) and again at 5, 10, 15 minutes after the injection

Method of measurement

Reynolds and Richmond Score

Secondary outcomes

1

Description

The duration of reaching a Reynolds and Richmond score less than one

Timepoint

At the beginning of the study (before the injection) and again at 5, 10, 15 minutes after the injection

Method of measurement

Reynolds and Richmond Score

2

Description

Side effects

Timepoint

60 minutes after the start of the intervention

Method of measurement

ECG to evaluate QT interval, blood pressure, heart rate, presence of seizures or hallucinations before and after receiving any of the drugs.

Intervention groups**1****Description**

Intervention group 1: receiving haloperidol 2.5 mg intramuscularly

Category

Treatment - Drugs

2**Description**

Intervention group 2: receiving ketamine at a dose of 20 mg

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital Complex

Full name of responsible person

Khalil Pestehei

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

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+98 912 608 5696

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khalilpesteh@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Keshavarz Blvd., corner of Quds St., Central Organization of the University, 6th floor

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1416634793

Phone

+98 21 8163 3698

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vcr@sina.tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Khalil Pestehei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Khalil Pestehei

Position

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Latest degree

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