# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 Squre, Tehran, Iran
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Tehran
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1419733141
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+98 912 608 5696
**Email**
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
**City**
Tehran
**Province**
Tehran
**Postal code**
1416634793
**Phone**
+98 21 8163 3698
**Email**
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
**Street address**
Keshavarz Blvd.Tehran
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## Person responsible for scientific inquiries

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Associate professor
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## Person responsible for updating data

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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