

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of single dose injection of ketamine in comparison with midazolam on acute suicidal thoughts in psychiatric patients: a double-blind clinical trial

#### Protocol summary

##### Study aim

The effect of ketamine in reducing suicidal ideation in short-term psychiatric patients

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 36 patients. Sampling was performed by available sampling. Using G\*POWER 3.1.9.2 software and assuming effect size = 0.4, alpha 0.05 and beta 0.2, three measurements and a correlation of 0.5 between measurements, the sample size was 18 in each group.

##### Settings and conduct

Study place: Rasoul Akram and Iran Hospital. The study population: clients of two above centers with acute suicidal ideation who were satisfied to participate in the study. Blinding: after admission, in collaboration with the treating physician and the supervisor, patients will receive medication or placebo based on a table of random numbers that the evaluator and analyst are unaware of the type of medication.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Clients with acute suicidal ideation; Age range of 18-68 years old. Non-inclusion criteria: physical disorders such as thyroid dysfunction, diabetes, hypertension, stroke and brain surgery and other neurological disorders; pregnant and lactating women; convulsion; recurrent and regular antidepressant drug use; psychosis

##### Intervention groups

Intervention group: Neurotic patients with suicidal ideation with single dose of ketamine injection, who will be interviewed by a psychiatrist, performed Hamilton test, VAS and BSSI. Control group: Patients with suicidal ideation receiving single dose of midazolam and similar evaluations of the intervention group

##### Main outcome variables

Score of Beck scale suicidal ideation; score of Visual

analog scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220118053756N1**

Registration date: **2022-06-12, 1401/03/22**

Registration timing: **retrospective**

Last update: **2022-06-12, 1401/03/22**

Update count: **0**

##### Registration date

2022-06-12, 1401/03/22

##### Registrant information

##### Name

maryam barzkar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4412 7505

##### Email address

maryam.barzkar@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-05-19, 1401/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of single dose injection of ketamine in comparison with midazolam on acute suicidal thoughts in psychiatric patients: a double-blind clinical trial

## Public title

The effect of single dose ketamine injection on reducing acute suicidal thoughts

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Clients with acute suicidal ideation (thoughts that have occurred within the last 72 hours and have not existed before, with serious risk and require psychiatric hospitalization) Age range of 18-68 years old

### Exclusion criteria:

physical disorders such as thyroid dysfunction, diabetes, hypertension, stroke and brain surgery and other neurological disorders History of abuse or allergy to ketamine or midazolam Pregnant and lactating women Convulsion current or recent and regular antidepressant medication last month

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Ketamine and midazolam are coded as A and B. A random sequence of A and B is created using a table of random numbers which is maintained by one of the researchers. The researcher prescribing the drug is not aware of the group to which the next patient is allocated until the moment of prescribing the drug. The intervention category of each patient is specified as A or B upon administration by contacting the researcher who has access to the sequence. Midazolam and ketamine are prepared in identical appearance, are labeled as A and B, and retained for the sole purpose of this research

## Blinding (investigator's opinion)

Double blinded

## Blinding description

participants and evaluators and analysts are not aware of the injection of the midazolam or Ketamine . The supervisor and the attending physician are aware of the injected drug. After randomization and receiving the code, the physician will be informed through the supervisor who is aware of the received code. The

evaluator and analyst will only know about group A or B. Ketamine and midazolam are both injectable and colorless and are prepared in normal saline and midazolam is injected at a low dose to reduce the sedative effect of it, which causes the study to go out of the double-blind state.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Research Ethics Committee

##### Street address

Tehran Hemat Highway next to Milad Tower. 14535

##### City

tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2020-04-19, 1399/01/31

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.069

## Health conditions studied

### 1

#### Description of health condition studied

Suicide

#### ICD-10 code

T14.91

#### ICD-10 code description

Suicide attempt

### 2

#### Description of health condition studied

Major depressive disorder

#### ICD-10 code

F32.2

#### ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

## Primary outcomes

### 1

#### Description

Beck suicidal questionnaire score

**Timepoint**

Before injection; after 12 hours; 24 hours later

**Method of measurement**

Beck suicidal questionnaire

**Secondary outcomes**

**1**

**Description**

Score of visual analog scale for suicidal ideation

**Timepoint**

Before injection; 12 hours and 24 hours after injection

**Method of measurement**

Self reporting by patient

**Intervention groups**

**1**

**Description**

Intervention group: patients with acute suicidal thoughts with ketamine injection 0.5 mg/kg

**Category**

Treatment - Drugs

**2**

**Description**

Control group: patients with acute suicidal thoughts with midazolam injection 0.02 mg/kg

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasool-e-akram hospital

**Full name of responsible person**

Maryam Barzkar

**Street address**

Niyayesh street; Sattarkhan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 8811

**Email**

maryam.barzkar@gmail.com

**2**

**Recruitment center**

**Name of recruitment center**

Iran psychiatric hospital

**Full name of responsible person**

Maryam Barzkar

**Street address**

Iran psychiatric hospital; Next to the entrance of North Azadegan Highway; 7th km of Karaj Makhsoos road; Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۹۸۹۱۳۱۵۱

**Phone**

+98 21 4450 3395

**Email**

iph@iums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein Keyvani

**Street address**

Iran University of Medical Sciences; next to Milad tower; Hemmat expressway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 8670 2503

**Email**

research-m@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences  
**Full name of responsible person**  
Maryam Barzkar  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Iran psychiatric hospital; Next to the entrance of  
North Azadegan Highway; 7th km of Karaj Makhsoos  
road; Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۳۹۸۹۱۳۱۵۱  
**Phone**  
+98 21 4450 3395  
**Email**  
maryam.barzkar@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Amir hossein Jalali Nadoushan  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Iran psychiatric hospital; Next to the entrance of  
North Azadegan Highway; 7th km of Karaj Makhsoos  
road; Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۳۹۸۹۱۳۱۵۱  
**Phone**  
0098 21 ۴۴۵۰۳۳۹۵۱  
**Email**  
drjalali57@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences  
**Full name of responsible person**  
maryam barzkar  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Iran psychiatric hospital; Next to the entrance of  
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**Phone**  
+98 21 4450 3395  
**Email**  
maryam.barzkar@gmail.com

## 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 encoding and being  
unrecognizable

### When the data will become available and for how long

Access period from 2021

### To whom data/document is available

Only for researchers working in academic and scientific  
institutions

### Under which criteria data/document could be used

Any kind of analysis is allowed if it is coordinated and the  
source is mentioned

### From where data/document is obtainable

Maryam Barzkar

### What processes are involved for a request to access data/document

Sending email to maryam.barzkar@gmail.com

### Comments