

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of injectable ketamine with doses of 0.5 mg/kg on the control of symptoms in patients with treatment-resistant major depressive disorder: a randomized clinical trial

#### Protocol summary

##### Study aim

Investigating the effect of using a single dose of intravenous ketamine on severe and treatment-resistant depression

##### Design

Clinical trial without control group, without parallel group, without blinding, without randomization, single phase on 15 patients

##### Settings and conduct

15 patients were selected according to the inclusion criteria and were given the Hamilton and Beck tests. Then the patients are admitted to Khatam al-Anbia hospital in Shahrood and receive 0.5 mg/kg of ketamine intravenously. This study is without randomization without blinding. Then they are observed for one hour in a stable and quiet room in Khatam Al Anbia Hospital. Then, after two days, one week, one month after the injection, Hamilton and Beck tests are taken from the patients again, and the Hamilton and Beck evaluation test scores are compared before and after the injection.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with depressive disorder based on DSM IV\_TR criteria Exclusion criteria : Respond to drug therapy or ECT - Cardiovascular problems and pregnancy

##### Intervention groups

The statistical population includes patients referred to Dr. Hojat Bastami's office who are suffering from treatment-resistant major depressive disorder according to DSM IV\_TR criteria and will be injected with 0.5mg/kg of ketamine intravenously as a single dose.

##### Main outcome variables

Severity of depression Cognitive complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230618058520N1**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

##### Registration date

2023-07-09, 1402/04/18

##### Registrant information

###### Name

Mohammad Shiroudi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4452 6920

###### Email address

dr7sina7sh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-05, 1402/04/14

##### Expected recruitment end date

2023-07-11, 1402/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of injectable ketamine with doses

of 0.5 mg/kg on the control of symptoms in patients with treatment-resistant major depressive disorder: a randomized clinical trial

#### Public title

Investigating the effect of using ketamine on severe and treatment-resistant depression

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with treatment-resistant major depressive disorder based on DSM IV \_ TR criteria Being in a depressive episode Failure to respond to antidepressants and shock medications and failure to control symptoms with other methods Intolerance of oral antidepressants

##### Exclusion criteria:

More serious psychiatric disorders: bipolar 1 and 2 - cyclothymia - psychosis - obsession - ski and affective Addiction or withdrawal from drugs Personality disorder Physical diseases such as: thyroid disorders, diabetes, hypertension, stroke, brain surgeries, etc. Response to drug treatment and control of disease symptoms with drugs Received ECT two months before starting ketamine treatment Receiving antidepressant medication one month before starting ketamine treatment Lack of consent to participate in the study Cardiovascular problems Pregnancy and breastfeeding

#### Age

No age limit

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: 15

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Shahrood Islamic Azad University

###### Street address

University Boulevard - Islamic Azad University

##### City

shahrood

##### Province

Semnan

##### Postal code

4318936199

##### Approval date

2022-09-14, 1401/06/23

##### Ethics committee reference number

IR.IAU.SHAHROOD.REC.1401.042

### Health conditions studied

#### 1

##### Description of health condition studied

depression

##### ICD-10 code

F33.9

##### ICD-10 code description

Major depressive disorder, recurrent, unspecified

### Primary outcomes

#### 1

##### Description

Depression score in Beck and Hamilton test.

##### Timepoint

Comparison of Hamilton and Beck test results before injection, two days after injection, one week after injection, one month after injection

##### Method of measurement

The criterion of response to ketamine treatment is a decrease of 50% or more in Beck and Hamilton tests.

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Intervention group: receiving 0.5mg/kg ketamine as a single intravenous dose - Rotex medica trittau germany

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Khatam al anbia hospital

###### Full name of responsible person

Yousef kolookhi

**Street address**

Khatam Al Anbia Hospital., Opposite Industrial University., University Blvd., Shahrood town

**City**

Shahrood

**Province**

Semnan

**Postal code**

3614871151

**Phone**

+98 23 2223 7807

**Email**

khatam@shahrood.ac.ir

**Web page address**

<https://shahrood.iau.ir/khatam-hospital/fa>

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mohammad shiroudi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Shahrood, Tehran Boulevard, Shahrood Islamic Azad University

**City**

Shahrood

**Province**

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**Postal code**

3613773955

**Phone**

+98 23 3239 1796

**Email**

dr7sina7sh@gmail.com

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

Vice Chancellor for Research and Technology, Shahrood Islamic Azad University

**Full name of responsible person**

Sahebali monafi

**Street address**

Khatam Al Anbia Hospital., Opposite Industrial, University Blvd., University., Shahrood town

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**Province**

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**Postal code**

3614871151

**Phone**

+98 23 3239 4279

**Email**

khatam@shahrood.ac.ir

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

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Shahrood Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Private

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

Islamic Azad University

**Full name of responsible person**

Yousef kolookhi

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Email**

dr.yousefkolookhi.anesthezia@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Mohammad shiroudi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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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