

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Efficacy of oral ketamine in treatment of patients with Major depressive disorder: A double - blind controlled trial

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of Ketamine as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. Fifty adult inpatient who meet the DSM- 5 criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 20 will be allocated into two groups. 25 patients will receive sertraline up to 150 mg/day plus ketamine 50mg/day and 25 participants will receive sertraline up to 150 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608071556N93**

Registration date: **2016-08-07, 1395/05/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-07, 1395/05/17

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral ketamine in treatment of patients with Major depressive disorder: A double - blind controlled trial

Public title

Efficacy of oral ketamine in treatment of patients with Major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 -60 years old; moderate to severe major depressive disorder based on Diagnostic & Statistical Mental Disorders (DSM-5); HRSD score above 20; signing informed consent. Exclusion criteria: receiving antidepressant drugs within the last month; cardiovascular disease; pregnancy and lactation; receiving ECT (Electroconvulsive Therapy) during the last two months; thyroid disease; alcohol & drug abuse.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

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

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2016-07-25, 1395/05/04

Ethics committee reference number

IR.TUMS.VCR.REC.1395.355

Health conditions studied**1****Description of health condition studied**

Major Depression

ICD-10 code

F32

ICD-10 code description

Major Depressive episode

Primary outcomes**1****Description**

Severity of depression

Timepoint

Baseline and weeks: 2, 4 and 6 after beginning of treatment

Method of measurement

Hamilton Depression Rating Scale 17-Item

Secondary outcomes

empty

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

Tablet sertraline up to 150 mg/day plus capsule ketamine 50 mg per day as intervention group for 6 weeks

Category

Treatment - Drugs

2**Description**

Tablet sertraline up to 150 mg/day plus placebo as control group for 6 weeks

Category

Placebo

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

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Street

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Tehran University of Medical Sciences, Keshvarz Blvd

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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*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work**Street address**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*