Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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 plusketamine 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

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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 above20; 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 beginig of treatment
Method of measurement
Hamiltion 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
City
Tehran
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
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Person responsible for updating data

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Web page address

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