

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Compression the efficacy of ketamine as bolus versus infusion with 0.5 mg /kg and 0.75 mg /kg in treatment of the major depressive disorder.

Protocol summary

Summary

The purpose of this study determine the effect of the anti depressant effects of ketamine in the treatment of patients with major depressive disorder. Methods and Sampling: clinical trial, simple randomized and single blind. 100 Patients with major depressive disorder according to DSM-V criteria with different severity and with out psychotic feature were selected. This patient also lacks a somatoform disorder and personality disorder co-morbidity, hypertension and heart disease and over the last month are not under medical treatment Randomly selected. In this study Patients into two groups of 50 at a dose of 0.5mg /kg and 0.75mg /kg divided and Each group was divided into two groups of 25 subjects following a single dose of intravenous bolus and infusion for 20 minutes and clinical psychologist at the pre-injection and the second day after injection and were interviewed Beck and Hamilton. More than 50% of patients who have the privilege of testing as respondents considered and again seven days, one month and two months after the administration of the tests turn back. Patients who have a score of less than 50% are considered as non-responders and they began to conventional therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030921072N2**
Registration date: **2015-04-04, 1394/01/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-04, 1394/01/15

Registrant information

Name

Farzan Kheirkhah

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1951

Email address

f.khairkhah@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compression the efficacy of ketamine as bolus versus infusion with 0.5 mg /kg and 0.75 mg /kg in treatment of the major depressive disorder.

Public title

Investigation of interavenous Ketamine anti depressant effects on major depressive disorder patients

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with major depressive disorder according to DSM-V criteria with different severity and with out psychotic feature were selected.this patient also lacks a

somatoform disorder and personality disorder co-morbidity, hypertension and heart disease and over the last month are not under medical treatment.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol College of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2015-03-10, 1393/12/19

Ethics committee reference number

5262

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Depression

Timepoint

Pre intervention, 2, 7, 30, 60 dayes post intervention

Method of measurement

Hamilton and Beck test

Secondary outcomes

1

Description

Drug dose

Timepoint

Pre intervention, 2, 7, 30, 60 dayes post intervention

Method of measurement

Hamilton and Beck test

2

Description

Method Of Injection

Timepoint

Pre intervention, 2, 7, 30, 60 dayes post intervention

Method of measurement

Hamilton and Beck test

Intervention groups

1

Description

Group 1= Single dose 0.5 mg/kg IV bolus

Category

Treatment - Drugs

2

Description

Group 2= Single dose 0.75 mg/kg IV bolus

Category

Treatment - Drugs

3

Description

Group 3= Single dose 0.5 mg/kg IV infusion

Category

Treatment - Drugs

4

Description

Group 4= Single dose 0.75 mg/kg IV infusion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Yahyanejad Hospital

Full name of responsible person

Doctor Gooya Tayyebi

Street address

Shahid Yahyanejad Hospital, Modares Avenue

City

Babol

2

Recruitment center

Name of recruitment center

Psychiatrists' office

Full name of responsible person

Doctor Farzan Kheirkhah

Street address

Building Pasargadae, Shahid Ghasemi Street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences, Research Deputy

Full name of responsible person

Doctor Ali Akbar Moghadamnia

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue

City

Babol

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

Yes

Title of funding source

Babol University of Medical Sciences, Research Deputy

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**

Shahid Yahyanejad Hospital

Full name of responsible person

Gooya Tayyebi

Position

Resident in Psychiatry

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

Shahid Yahyanejad Hospital, Modares Avenue

City

Babol

Postal code

4713566547

Phone

+98 11 3229 1951

Fax

+98 981132291951

Email

G.Tayyebi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Babol University Of Medical Sciences

Full name of responsible person

Farzan Kheirkhah

Position

Associate Professor Of Psychiatry

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

Babol University Of Medical Sciences, Ganj afrooz Avenue

City

Babol

Postal code

4713566547

Phone

+98 11 3229 1951

Fax

+98 11 3229 1951

Email

Drfarzankh@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Yahyanejad Hospital

Full name of responsible person

Gooya Tayyebi

Position

Psychiatry Resident

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

Shahid Yahyanejad Hospital, Modares Avenue

City

Babol

Postal code

4713566547

Phone

+98 11 3229 1951

Fax

Email

G.Tayyebi@yahoo.com

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