Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparing the effectiveness of ketamine and placebo on suicidal ideation

Protocol summary

Study aim
Determining the effectiveness of ketamine on suicidal thoughts

Design
Clinical trial, double-blind, phase three, randomized, which will be conducted on 90 patients.

Settings and conduct
The studied population is patients over 18 years of age admitted to the psychiatric department of Shahid Yaheinejad Hospital who have a major depressive episode based on DSM-5 psychiatric clinical interview and have a score of more than 5 on the Beck suicidal ideation scale according to the numerical table method. Randomly divided into two groups by subsidy and intervention will be done on them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having a major depressive episode based on a clinical interview (based on DSM-5)؛ a total score of more than 5 on the Beck Suicidal Thoughts Scale؛ a score of 14 or higher on the Beck Depression Inventory؛ absence of pregnancy or breastfeeding؛ Absence of obvious cognitive impairment or mental retardation

Intervention groups
Intervention group: Ketamine with a dose of 0.75-0.50 mg/kg as a 40-minute infusion. Control group: 0.9% saline as a 40-minute infusion

Main outcome variables
suicidal ideation Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190317043079N4**
Registration date: **2023-04-25, 1402/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-25, 1402/02/05**
Update count: **0**

Registration date
2023-04-25, 1402/02/05

Registrant information

Name
farzan kheirkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3229 1951

Email address
f.kheirkhah@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-25, 1402/02/05

Expected recruitment end date
2024-04-24, 1403/02/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of ketamine and placebo on suicidal ideation

Public title
The effectiveness of ketamine on suicidal ideation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
having a major depressive episode based on a clinical interview (based on DSM-5) A total score of more than 5 on the Beck suicidal ideation scale A score of 14 or

higher in the Beck depression questionnaire Absence of pregnancy or lactation Absence of obvious cognitive impairment or mental retardation

Exclusion criteria:

Receiving psychiatric medications within a month before starting ketamine treatment History of sensitivity to ketamine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using permutation blocks of size 4 (AABB). Patients will be randomly assigned to two groups of 45 using 25 blocks of size 4 and 1:1 ratio. Creating a random sequence in the blocks will be done by a statistician through the block randomization site

Blinding (investigator's opinion)

Double blinded

Blinding description

The solutions required for infusion (ketamine 0.5mg/kg and ketamine 0.75mg/kg and placebo containing 0.9% saline) are prepared by the pharmacology expert consultant of the project in similar shape, size and color and are available to the specialist assistant of psychiatry who is the project manager. will be placed The solutions are coded separately and only the pharmacology specialist will know about the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Health research institu-Babol University of Medical Siences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.292

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F06.32

ICD-10 code description

Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

Suicidal Ideation

Timepoint

48 hours after receiving the infusion

Method of measurement

Beck scale suicide ideation questionaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ketamine with a dose of 0.75-0.50 mg/kg as a 40-minute infusion

Category

Treatment - Drugs

2

Description

Control group: 0.9% saline as a 40-minute infusion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nezhad Hospital

Full name of responsible person

Farzan Kheirkhah

Street address

Shahid Mostafa Khomeini St, Modarres St
City
Babol
Province
Mazandaran
Postal code
4713566547
Phone
+98 11 3222 5035
Email
f.kheirkhah@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
Street address
Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4713566547
Phone
+98 11 3219 7667
Email
m.rajabnia@mubabol.ac.ir
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
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
Babol University of Medical Sciences
Full name of responsible person
Farzan Kheirkhah
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4713566547
Phone
+98 11 3233 8301
Email
f.kheirkhah@mubabol.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Farzan Kheirkhah
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4713566547
Phone
+98 11 3233 8301
Email
f.kheirkhah@mubabol.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Farzan Kheirkhah
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

City
Babol
Province
Mazandaran
Postal code
4713566547
Phone
+98 11 3233 8301
Email
f.kheirkhah@mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information

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