

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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 questionnaire

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

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Shahid Mostafa Khomeini St, Modarres St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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