Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of single dose injection of ketamine in comparison with midazolam on acute suicidal thoughts in psychiatric patients: a double-blind clinical trial

Protocol summary

Study aim
The effect of ketamine in reducing suicidal ideation in short-term psychiatric patients

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 36 patients. Sampling was performed by available sampling. Using G * POWER 3.1.9.2 software and assuming effect size = 0.4, alpha 0.05 and beta 0.2, three measurements and a correlation of 0.5 between measurements, the sample size was 18 in each group.

Settings and conduct
Study place: Rasoul Akram and Iran Hospital. The study population: clients of two above centers with acute suicidal ideation who were satisfied to participate in the study. Blinding: after admission, in collaboration with the treating physician and the supervisor, patients will receive medication or placebo based on a table of random numbers that the evaluator and analyst are unaware of the type of medication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Clients with acute suicidal ideation; Age range of 18-68 years old. Non-inclusion criteria: physical disorders such as thyroid dysfunction, diabetes, hypertension, stroke and brain surgery and other neurological disorders; pregnant and lactating women; convulsion; recurrent and regular antidepressant drug use; psychosis

Intervention groups
Intervention group: Neurotic patients with suicidal ideation with single dose of ketamine injection, who will be interviewed by a psychiatrist, performed Hamilton test, VAS and BSSI. Control group: Patients with suicidal ideation receiving single dose of midazolam and similar evaluations of the intervention group

Main outcome variables
Score of Beck scale suicidal ideation; score of Visual analog scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220118053756N1**
Registration date: **2022-06-12, 1401/03/22**
Registration timing: **retrospective**

Last update: **2022-06-12, 1401/03/22**
Update count: **0**

Registration date
2022-06-12, 1401/03/22

Registrant information

Name
maryam barzkar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4412 7505

Email address
maryam.barzkar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-05-19, 1401/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of single dose injection of ketamine in comparison with midazolam on acute suicidal thoughts in psychiatric patients: a double-blind clinical trial

Public title
The effect of single dose ketamine injection on reducing acute suicidal thoughts

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Clients with acute suicidal ideation (thoughts that have occurred within the last 72 hours and have not existed before, with serious risk and require psychiatric hospitalization) Age range of 18-68 years old
Exclusion criteria:
physical disorders such as thyroid dysfunction, diabetes, hypertension, stroke and brain surgery and other neurological disorders History of abuse or allergy to ketamine or midazolam Pregnant and lactating women Convulsion current or recent and regular antidepressant medication last month

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Ketamine and midazolam are coded as A and B. A random sequence of A and B is created using a table of random numbers which is maintained by one of the researchers. The researcher prescribing the drug is not aware of the group to which the next patient is allocated until the moment of prescribing the drug. The intervention category of each patient is specified as A or B upon administration by contacting the researcher who has access to the sequence. Midazolam and ketamine are prepared in identical appearance, are labeled as A and B, and retained for the sole purpose of this research

Blinding (investigator's opinion)
Double blinded

Blinding description
participants and evaluators and analysts are not aware of the injection of the midazolam or Ketamine . The supervisor and the attending physician are aware of the injected drug. After randomization and receiving the code, the physician will be informed through the supervisor who is aware of the received code. The evaluator and analyst will only know about group A or B.Ketamine and midazolam are both injectable and colorless and are prepared in normal saline and midazolam is injected at a low dose to reduce the sedative effect of it, which causes the study to go out of the double-blind state.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Research Ethics Committee

Street address
Tehran Hemat Highway next to Milad Tower، 14535

City
tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2020-04-19, 1399/01/31

Ethics committee reference number
IR.IUMS.FMD.REC.1399.069

Health conditions studied

1

Description of health condition studied
Suicide

ICD-10 code
T14.91

ICD-10 code description
Suicide attempt

2

Description of health condition studied
Major depressive disorde

ICD-10 code
F32.2

ICD-10 code description
Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

Beck suicidal questionnaire score

Timepoint

Before injection; after 12 hours; 24 hours later

Method of measurement

Beck suicidal questionnaire

Secondary outcomes

1

Description

Score of visual analog scale for suicidal ideation

Timepoint

Before injection; 12 hours and 24 hours after injection

Method of measurement

Self reporting by patient

Intervention groups

1

Description

Intervention group: patients with acute suicidal thoughts with ketamine injection 0.5 mg/kg

Category

Treatment - Drugs

2

Description

Control group: patients with acute suicidal thoughts with midazolam injection0.02 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e-akram hospital

Full name of responsible person

Maryam Barzkar

Street address

Niyayesh street; Sattarkhan street

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person
Maryam Barzkar

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Specialist

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Latest degree
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Other areas of specialty/work
Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after encoding and being unrecognizable

When the data will become available and for how long
Access period from 2021

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
Any kind of analysis is allowed if it is coordinated and the source is mentioned

From where data/document is obtainable
Maryam Barzkar

What processes are involved for a request to access data/document
Sending email to maryam.barzkar@gmail.com

Comments