

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

A Comparative Study of the Efficacy of Ketamine versus Sodium Thiopental as Anesthetic Agents in Electroconvulsive Therapy (ECT) on Reducing Depressive Symptoms and Suicidal Ideation in Patients with Major Depressive Disorder

Protocol summary

Study aim

Comparison of the effectiveness of Ketamin and Sodium Thiopental in ECT anesthesia on reducing depressive symptoms and suicidal ideation in patients with Major Depressive Disorder(MDD)

Design

Clinical trial with two intervention groups with parallel groups, double-blind, randomized, phase 2 on 34 patients

Settings and conduct

The study will be performed in Zanjan and the ECT room of the hospital and Patients receive Atropine before receiving anesthetics, then the ketamine group receives two mg/kg of ketamine and the sodium thiopental group receives two to three mg/kg of sodium thiopental and will be anesthetized. After anesthesia, the muscle relaxant Succinylcholine will be injected into the patient at a rate of half a mg/kg and the patient will be ventilated with an oxygen mask and 100% oxygen during anesthesia. Then ECT will be performed bilaterally, 3 times a week and for 6 sessions, following standard protocols. After completing the ECT sessions, the Montgomery Inventory will be used to assess depression and suicidal thoughts. Data collection will be completed again after 6 ECT sessions and also 4 weeks after the end of the sessions. Patients, investigators, outcome assessors, and data analysts will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria included individuals aged 18 years and older of both genders with a diagnosis of MDD and suicidal Ideation. Exclusion criteria included having a diagnosis other than MDD and having contraindications to ECT.

Intervention groups

The study has a group receiving ketamine and a group receiving thiopental for ECT. The ketamine group

receives 2 mg/kg of ketamine before receiving ECT, and the sodium thiopental group receives 2 to 3 mg/kg of sodium thiopental and is anesthetized. Then, ECT will be performed bilaterally

Main outcome variables

Age; Gender; Education; Marital status; Depressive symptoms; Suicidal Ideation

General information

Reason for update

Acronym

ECT

IRCT registration information

IRCT registration number: **IRCT20241203063932N1**

Registration date: **2025-08-02, 1404/05/11**

Registration timing: **prospective**

Last update: **2025-08-02, 1404/05/11**

Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Sadaf Danehzan

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of the Efficacy of Ketamine versus Sodium Thiopental as Anesthetic Agents in Electroconvulsive Therapy (ECT) on Reducing Depressive Symptoms and Suicidal Ideation in Patients with Major Depressive Disorder

Public title

Comparison of Ketamine and Sodium Thiopental effects in Electroconvulsive Therapy anesthesia on Depression and Suicidal Ideation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18 years and older of all genders MDD diagnosis confirmed by DSM-V criteria Active Suicidal Ideation Written informed consent

Exclusion criteria:

Patients with Bipolar Mood Disorder Patients with Schizophrenia Patients with Schizoaffective Disorder History of Substance abuse within the past Three Months History of significant adverse effects associated with Anesthetic agents History of Cardiovascular Diseases Patients with body Implants(e.g., Pacemakers, Intracranial Electrodes, etc.) Pregnant Women Contraindications to ECT(e.g., extensive Brain lesions, elevated Intracranial Pressure and recent Myocardial Infarction) Non-consenting individuals History of Hypertension, Cardiac conduction disorders and Tachycardia

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **34****Randomization (investigator's opinion)**

Randomized

Randomization description

Convenience sampling will be performed among eligible patients. Patients will be assigned to two study groups using block randomization. In each block of 2, one

patient will be assigned to the Ketamine group and one patient to the Sodium Thiopental group. Random sequences will be generated using Random Allocation Software and allocation concealment will be used to prevent bias. The generated sequences will be placed in sealed envelopes and maintained by an independent person from the research team. After final confirmation of the patient's eligibility, the relevant envelope will be opened and the treatment group will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the drugs are similar in appearance, color, and volume, participants (patients) will be kept blind and will not know which group (Ketamine or Sodium Thiopental) they are in. Clinical observers, including the Anesthesiologist and Anesthesia Technician, will be unblinded to group patients, determine the type of drug and its injection, and control possible side effects. The principal investigator (supervisors and myself) will be blinded to prevent bias and will only see the group numbers. Outcome assessors, including the Psychiatrist who records the Depression score, will be blinded. The data analyst will be blinded and the data will be presented with group codes so that the analyst is unaware of the actual allocation, and the codes will be opened after the initial analysis is complete. The safety and data monitoring committee will be unblinded to learn about the details of the interventions and side effects.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

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Professor Sobouti Blvd., Karmandan Town., Gavazang Road

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Postal code

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Approval date

2025-04-08, 1404/01/19

Ethics committee reference number

IR.ZUMS.REC.1404.032

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

Primary outcomes

1

Description

Depression score on the Montgomery-Åsberg Depression Rating Scale

Timepoint

Depression and suicidal ideation will be assessed before starting ECT with ketamine and sodium thiopental, after 6 ECT sessions, and also 4 weeks after completing the sessions.

Method of measurement

Montgomery-Åsberg Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Ketamine, an anesthetic and NMDA receptor antagonist, is administered intravenously to patients at a dose of 2 mg/kg before ECT.

Category

Treatment - Drugs

2

Description

Intervention group 2: Thiopental sodium, an anesthetic drug, is injected intravenously at a dose of two to three milligrams per kilogram before ECT.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Sadaf Danehzan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Sadaf Danehzan

Position

Resident

Latest degree

Medical doctor

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

In this study, data related to participants, such as depressive symptoms reported before and after receiving treatment and information related to the main outcome (depression score on the Montgomery Depression Inventory), will be shared after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Study data and documentation will be available to medical universities, academic institutions, and psychiatric hospitals. Study data and documentation will be available to medical universities, academic institutions, and psychiatric hospitals.

Under which criteria data/document could be used

Data and documents will be available in a non-personally identifiable form to individuals active in academic and scientific systems for additional research and review, presentation in groups and classes, and for uploading to cyberspace for education

From where data/document is obtainable

To receive data, my email address is sa.dnzn@gmail.com and my work address is Zanjan-Shahid Beheshti Psychiatric Hospital. Dr Sadaf Danehzan

What processes are involved for a request to access data/document

To receive the documents, applicants must email me their details along with the reason for requesting the materials. After reviewing the details and relevant materials, the documents will be sent via email within a week.

Comments