Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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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Iran (Islamic Republic of)

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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
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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
Street address
Professor Sobouti Blvd., Karmandan Town., Gavazang Road
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Zanjan
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Postal code
۴۵۱۳۹۵۶۱۸۴
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
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Person responsible for updating data

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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