Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of the effect of combining Ketamine-Propofol and Ketamine- Thiopental during Electroconvulsive Therapy in Reducing the Symptoms in Patients with Major Depression Disorder :a clinical trial

Protocol summary

Study aim

The aim of this study was to compare the effect of ketamine-propofol combination with ketamine-thiopental during electroconvulsive therapy(ECT) anesthesia in improving depressive symptoms in patients diagnosed with major depression.

Design

Clinical trial, with parallel groups, not blinded, randomized, phase 3 on 60 patients, used to randomize the quadruple block.

Settings and conduct

60patients between the ages of 18 and 59 years, with a definite diagnosis of refractory depressive disorder, who have been referred to the psychiatric ward of Kowsar Hospital in Semnan, are admitted to the study after applying the inclusion and exclusion criteria. The patients are divided into two groups. At first, 0.5 mg of atropine is administered. After one minute, thiopental-ketamine is given to the first group and propofol-ketamine to the second group. Grams are prescribed per kilogram of patient weight. After one minute, shock is given as prescribed and the duration of seizures is recorded for each patient. 6 ECT sessions are performed for all samples and before the beginning of the first ECT session and at the end of the third and sixth sessions, Beck depression test is taken from all samples.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of moderate to severe depression; age at least 18 years; having informed consent; ECT history in the last 6 months; Exclusion criteria: conscious dissatisfaction; anorexia nervosa; ECT in the last three months; contraindications for ECT; development of psychotic symptoms; or exacerbation of depressive symptoms during the study.

Intervention groups

Intervention group: 30 patients under anesthesia with thiopental combination at a dose of 3 mg/kg with ketamine at a dose of 0.5 mg/kg Control group: 30 patients under anesthesia with a combination of propofol at a dose of 1.5 mg/kg with ketamine 0.5 mg/kg

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211009052708N1**
Registration date: **2021-10-28, 1400/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-28, 1400/08/06**
Update count: **0**

Registration date

2021-10-28, 1400/08/06

Registrant information

Name

Aysan Taravati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Comparison of the effect of combining Ketamine-Propofol and Ketamine- Thiopental during Electroconvulsive Therapy in Reducing the Symptoms in Patients with Major Depression Disorder :a clinical trial

Public title
Comparison of the effect of ketamine-propofol combination with ketamine-thiopental in improving depressive symptoms in patients undergoing electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Includes: Diagnosis of moderate to severe depression episode affected by DSM-5 age at least 18 years performance and willingness to provide written consent by patient or legal guardian verbal IQ of 8.5 or greater undergoing ECT treatment in the past six months To be caught
Exclusion criteria:
Inability to provide informed written consent in the absence of a legal guardian primary psychotic or schizoaffective disorder obsessive-compulsive disorder concomitant diagnosis of multiple psychiatric disorders in axis one and two anorexia nervosa history of substance or alcohol dependence sensitivity to Anesthesia drugs or contraindications for their administration ECT in the last three months contraindications for ECT such as organic brain diseases and dementia major medical conditions that affect neuropsychological function pregnancy or lack of proper contraception breastfeeding Occurrence of psychotic symptoms or exacerbation of depressive symptoms during the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 15 blocks to select 60 people. We randomly select these blocks from the numbers 1 to 6.Using R software, we choose a random number between the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the forth block. The people who enter the study are given B-A-A-BA- A-B-B, respectively.Finally, group 1 and group 2 will be identified.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan University of Medical Sciences - Research and development Vice
Street address
Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2021-10-04, 1400/07/12
Ethics committee reference number
IR.SEMUMS.REC.1400.150

Health conditions studied

1

Description of health condition studied
Depression
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
Depression score in Beck questionnaire
Timepoint
Before the start of the first ECT session and at the end of the third and sixth sessions, the Beck Depression Inventory test is performed on all samples.
Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description
Quality of life score
Timepoint
After the end of the treatment period
Method of measurement
Short questionnaire SF-12

Intervention groups

1

Description
Intervention group: Combination of thiopental at a dose of 3 mg / kg with ketamine at a dose of 0.5 mg / kg after administration of 0.5 mg atropine at the beginning of ECT
Category
Treatment - Drugs

2

Description
Control group: Combination of 1.5 mg /kg propofol with 0.5 mg/kg of ketamine patient after 0.5 mg atropine at the beginning of ECT
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital in Semnan
Full name of responsible person
Aysan Taravati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abolfazl Abdollahpoor
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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
Semnan University of Medical Sciences
Proportion provided by this source
50
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
Semnan University of Medical Sciences
Full name of responsible person
Aysan Taravati
Position
Resident Anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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