

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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)

Phone

+98 11 4423 2234

Email address

dr.a.taravati@gmail.com

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

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Semnan University of Medical Sciences

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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

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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

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