# 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
**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
**Street address**
Kowsar Hospital in Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3519899951
**Phone**
+98 23 3344 1022
**Fax**
+98 23 3343 7837
**Email**
kosarhos@semums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Abolfazl Abdollahpoor
**Street address**
Semnan University of Medical Sciences
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3344 1022
**Fax**
**Email**
info@semums.ac.ir
**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**
Anesthesiology
**Street address**
Semnan University of Medical Sciences
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3344 1022
**Email**
dr.a.taravati@gmail.com

## Person responsible for scientific 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**
Anesthesiology
**Street address**
Semnan University of Medical Sciences
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3344 1022
**Email**
dr.a.taravati@gmail.com

## Person responsible for updating data

**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**
Anesthesiology
**Street address**
Semnan University of Medical Sciences
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3344 1022
**Email**
dr.a.taravati@gmail.com

## 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