Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

A DOUBLE BLIND CLINICAL RANDOMIZED TRIAL OF ASSESSMENT OF KETAMINE ADDED TO PROPOFOL ON MMSE SCORE AFTER ECT IN MAJOR DEPRESSION PATIENTS

Protocol summary

Summary

This study will perform in 120 patients between 18-60y with major depression ,who meet the DSM-TR IV, and candidate for electroconvulsive therapy in Shafa Hospital, in 2015.This elective procedure is performed only in 1th session of ECT .The exclusion criteria in the study is consist of the patients with ASA class IV any cognitive disorder from mild to moderate ,emergency situation ,history of cardiovascular disease,mental retardation and uncontrolled hypertension. Design of study is double blind, randomized with control group. Informed conscience will taken for every patient. In control group, after iv access preparation the patients will receive ketofol mixture (ketamine 0.5 mg/kg and propofol 0.5mg/kg)and the suuccynilcholine for relaxation. In control group the patients will receive propofol 1mg/kg with equal volume of ketamine that prepare by normal saline. The patients will ventilate by bag and mask with 100% of oxygen till the energy will delivered to patients in bitemporal electrode mode insertion. The patients will observe in recovery until to fully awake position. Time of seizure and time of awakening also will record. All the patients are visited by psychiatrist to evaluate the Mini Mental Status Examination before and 5 and 24 hours after ECT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503266280N6**
Registration date: **2015-04-29, 1394/02/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-04-29, 1394/02/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Guilan University Of Medical Sciences Research And Technology Secretary

Expected recruitment start date

2015-05-06, 1394/02/16

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A DOUBLE BLIND CLINICAL RANDOMIZED TRIAL OF ASSESSMENT OF KETAMINE ADDED TO PROPOFOL ON MMSE SCORE AFTER ECT IN MAJOR DEPRESSION PATIENTS

Public title

The Compsrison Between Two Drug Ketamine and Propofol On Cognition After ECT

Purpose
Prevention
Inclusion/Exclusion criteria
The inclusion criteria are the patients with major depression ; the age between 18-60; who meet the DSM-IV-R criteria and candidate for elective electroconvulsive therapy. The exclusion criteria are any cognition problem before ECT ;history of mental retardation; uncontrolled hypertension; history of recent ECT administration and patients with ASA class IV that will exclude from the study.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
we used electronical softwre to generate the random allocation sequence.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University Of Medical Sciences
Street address
Namjoo Avenue, Deputy department OF Guilan University Of Medical Sciences
City
Rasht
Postal code
4193833697
Approval date
2015-02-24, 1393/12/05
Ethics committee reference number
1930596703

Health conditions studied

1

Description of health condition studied
MAJOR DEPRESSION
ICD-10 code
F32
ICD-10 code description
F32.2

Primary outcomes

1

Description
MMSE mini mental Status exam
Timepoint
Before the electroconvulsive therapy and 5 and 24 hours after ECT procedure.
Method of measurement
MMSE mini mental Status exam 24-30, NO COGNITIVE PROBLEM 23-18MILD COGNITIVE PROBLEM 0-17,SEVER COGNITIVE PROBLEM

Secondary outcomes

1

Description
seizure duration
Timepoint
seizure production
Method of measurement
based on time (sec)

Intervention groups

1

Description
In intervention group , patients will receive ketofol (ketamine 0.5 mg/kg , propofol 0.5 mg/kg mixture)and the suuccynilcholine for relaxation. The patients will ventilate by bag and mask with 100% of oxygen till the bitemporal electrode will insert.
Category
Treatment - Drugs

2

Description
In control group the patients will receive propofol 1mg/kg with equal volume of ketamine that prepare by normal saline. The patients will ventilate by bag and mask with 100% of oxygen till the bitemporal electrode will insert. The patients will observe in recovery until to fully awake position. Time of seizure and time of awakening also will record
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital ,Teaching And Research Center
Full name of responsible person
Mohammad Haghighi
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research OF Guilan University of Medical Sciences
Full name of responsible person
Abtin Heydarzadeh Dr
Street address
Shahid beheshti Highway Rasht Guilan Iran, Islamic Republic Of
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor For Research OF Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty