

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

Name

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Name of organization / entity

Guilan University of Medical Sciences

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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 software 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

Rasht

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

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Shahid beheshti Highway Rasht Guilan Iran, Islamic Republic Of

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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

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

Contact

Name of organization / entity

Guilan University of Medical Sciences /RASHT /IRAN

Full name of responsible person

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Full name of responsible person

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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