

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the incidence and severity of cognitive impairment after electroconvulsive therapy under general anesthesia with remifentanyl in patients referred to electroconvulsive therapy shaft center , Rasht in 1395

Protocol summary

Summary

(1) Objectives: The aim of this study is to assess the cognitive function (memory) following electroconvulsive therapy in patients who receive remifentanyl as sole agent anesthetic. (2) Design: This study has been designed as a double blind randomized controlled clinical trial. (3) Setting and conduct: In the electroconvulsive therapy ward the informed consents will taken for every patient and the minimal status examination will described to patients. After intravenous access preparation, In drug group, the patients will receive remifentanyl 4-8µg/kg, and the succinylcholine 0.5 mg/kg for relaxation. In control group the patients will receive, thiopental with equal volume of that prepare by normal saline. The patients will ventilate by bag and mask with 100% of oxygen till the bi-temporal electrode will insert. The patients will observe in recovery until to fully awake position. Time of seizure and time of awakening will also recorded. All the patients are visited by psychiatrist to evaluate the minimal status examination before and 5 and 24 hours after electroconvulsive therapy. (4) Participants including major eligibility criteria This study will perform in 60 patients between 18-60 with major depression, who meet the DSM-TR IV, in shafa hospital, in 2016. This elective electroconvulsive therapy will performed only in 1th session of electroconvulsive therapy. The exclusion criteria in the study is consist of the patients with ASA class IV , mild to moderate cognitive disorder, emergency condition, history of cardiovascular disease, mental retardation and uncontrolled hypertension. (5) Intervention: In drug group, the patients will receive remifentanyl 4-8µg/kg, and the succinylcholine 0.5 mg/kg for relaxation. In control group the patients will receive, thiopental with equal volume of that prepare by normal saline. (6) Main outcome measures (variables): The primary outcome:

MiniMental Status Examination(MMSE) Scoring.

Secondary outcome: Duration of Seizure, Hemodynamic Parameter, Time of awakening ,nausea , vomiting and pruritis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608086280N10**

Registration date: **2016-10-02, 1395/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Mohammad Haghghi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Guilan University of Medical Sciences

Expected recruitment start date

2016-09-05, 1395/06/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the incidence and severity of cognitive impairment after electroconvulsive therapy under general anesthesia with remifentanil in patients referred to electroconvulsive therapy shaft center , Rasht in 1395

Public title

The Effect of remifentanil on Mini-mental status examination after electroconvulsive therapy in major depressive patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 60 patients between 18-60y; major depression; meet the DSM-TR IV ;. elective electroconvulsive therapy will performed only in 1th. The exclusion criteria : the patients with ASA class IV ; mild to moderate cognitive disorder; emergency condition; history of cardiovascular disease; mental retardation ; uncontrolled hypertension.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical

Sciences

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Shahid Beheshti Highway

City

Rasht

Postal code

4193893345

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.GUMS.REC.1395.111

Health conditions studied**1****Description of health condition studied**

The Patients With Major Depressive Disease

ICD-10 code

F32-3

ICD-10 code description

Severe depressive episode with psychotic symptoms

Primary outcomes**1****Description**

Cognitive Disorder after ECT

Timepoint

Before the ElectroConvulsive Therapy and 5 and 24 hours after ECT procedure.

Method of measurement

MMSE Questionnaire 24-30, no cognitive problem
23-18mild cognitive problem 0-17,sever cognitive problem

Secondary outcomes**1****Description**

Heart Rate

Timepoint

before electro convulsive therapy /5 and 24 hour after ECT.

Method of measurement

ECG

2**Description**

Blood Presssure.

Timepoint

the time before electro convulsive therapy /5 and 24 hour after ECT.

Method of measurement

NonInvasive Blood Pressure .

3**Description**

Seizure Duration .

Timepoint

before electro convulsive therapy /5 and 24 hour after ECT.

Method of measurement

By chronometer.

Intervention groups

1

Description

In intervention group , the patients will receive remifentanil as the sole agent anesthetic with doses : 4-8 µg/kg ,and the succinylcholine will administered for relaxation.The patients will ventilate by bag and mask with 100% of oxygen till the bi-temporal electrode will insert. 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 evaluated the minimal status examination before and 5 and 24 hours after electro convulsive therapy.

Category

Treatment - Drugs

2

Description

In control group the patients will receive thiopental 4 mg/kg with equal volume of that prepare by normal saline. The patients will ventilated by bag and mask with 100% of oxygen till the bi-temporal electrode will insert. 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 evaluated the (Mini Mental Status Exam) MMSE before and 5 and 24 hours after electro convulsive therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital PsychiatryCenter, Rasht

Full name of responsible person

Mohammad Haghighi

Street address

Anesthesiology Research Center, Poursina Hospital,
Cross poursina, Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of
Medical Sciences

Full name of responsible person

Shadman Nemati Dr

Street address

Shahid Beheshti Highway

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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, 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

Anesthesiology Research Center, Guilan University Of
Medical Sciences

Full name of responsible person

DrMohammad Haghighi

Position

Associate Professor,Anesthesiologist

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work**Street address**

Poursina Hospital ,Parastar St , Rasht

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