Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

(1) Objectives: The aim of this study is to assess the cognitive function (memory) following electroconvulsive therapy in patients who receive remifentanil 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 minimental status examination will described to patients. After intravenous access preparation, In drug group, the patients will receive remifentanil 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 minimental 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 remifentanil 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

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Name of organization / entity

Guilan University of Medical Sciences

Country

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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
Street address
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 suuccynilcholine will administerd 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 minimental 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

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, 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

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Position

Associate Professor,Anesthesiologist

Other areas of specialty/work

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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