Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

Comparison of the incidence and severity of cognitive impairment after electroconvulsive therapy under general anesthesia in the two groups with remifentanil- thiopental sodium thiopental - placebo in patients referred to ECT Center shafa of Rasht in 2013

Protocol summary

Summary

This prospective, randomized study aimed to compare the incidence and severity of cognitive impairment after electroconvulsive therapy under general anesthesia in the two groups with remifentanil - thiopental sodium or placebo- sodium thiopental. This study is double blind. 120 patients, aged 18-60 years old with psychiatric disorders diagnosed by psychiatrists according to DSMIV-TR criteria and candidates for ECT enroll in the study. Exclusion criteria are emergency ECT; severe cognitive dysfunction prior to ECT; history of mental retardation; severe heart disease; history of previous ECT; ASA physical status III-IV; uncontrolled hypertension and needs to treat agitation after ECT. The patients randomly assigned into groups of 60 to receive remifentanil 50 mic plus thiopental sodium (study group)or normal salin plus thiopental sodium (control group) in both the volume of 5 ml. Severity of cognitive impairment will assess by psychiatrists before ECT, 5 hours and 24 hours after electroconvulsive therapy with the test mini mental status exam (MMSE).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306086280N2**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name
Mohammad Haghighi

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 13 3211 1319

Email address
mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the incidence and severity of cognitive impairment after electroconvulsive therapy under general anesthesia in the two groups with remifentanil-thiopental sodium thiopental - placebo in patients referred to ECT Center shafa of Rasht in 2013

Public title

The effect of remifentanil - thiopental sodium on cognitive impairment after electroconvulsive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with psychiatric disorders diagnosed by psychiatrists according to DSMIV-TR criteria; age between 18-60 years old; signing informed consent; ASA physical status I or II; ECT candidates for the first time. Exclusion criteria: emergency ECT; severe cognitive dysfunction prior to ECT; history of mental retardation; severe heart disease; history of previous ECT; ASA physical status III-IV; uncontrolled hypertension and needs to treat agitation after ECT.

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences, Research and Technology

Street address

shahid beheshti Highway - End of the Skyway - up Iran Radiator

City

rasht

Postal code

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

2920029709

Health conditions studied

1

Description of health condition studied

Patient with psychiatric disorder

ICD-10 code

F10-39

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use,Schizophrenia, schizotypal and delusional disorders,Mood [affective] disorders

Primary outcomes

1

Description

incidence of cognitive impairment after electroconvulsive therapy in general anesthesia with remifentani plus thiopental sudium

Timepoint

Before ECT, 5 hours and 24 hours after ECT

Method of measurement

By testing mini mental status exam (MMSE)

2

Description

severity of cognitive impairment after electroconvulsive therapy in general anesthesia with remifentani plus thiopental sudium

Timepoint

Before ECT, 5 hours and 24 hours after ECT

Method of measurement

By testing mini mental status exam (MMSE)

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before induction of anesthesia, immediately after ECT, after entering the recovery

Method of measurement

By electronic sphygmomanometer in the ECT room

2

Description

Heart rate

Timepoint

Before induction of anesthesia, immediately after ECT, after entering the recovery

Method of measurement

By monitoring heart rate

Intervention groups

1

Description

Intervention group: remifentanil 50 mic plus thiopental sodium

Category

Treatment - Drugs

2

Description
Control group:normal salin plus thiopental sodium
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa hospital
Full name of responsible person
Dr.mohammad haghighi
Street address
Shahid beheshti Kamarbandi, Khordad 15 street, Heshmat crossroads
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences,Research and Technology
Full name of responsible person
Dr. Rasoul Tabari(MD)
Street address
Shahid Beheshti Highway, End of the Skyway, Above iran radiator
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences,Research and Technology
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 and Critical Care Research Centre
Full name of responsible person
Dr. Mohammad Haghighi
Position
Anesthesiologist, associate professor
Other areas of specialty/work
Street address
Namjoo street, Velaiat hospital
City
Rasht
Postal code
4193833697
Phone
+98 13 1321 0424
Fax
+98 13 1324 5140
Email
mohaghighi@gums.ac.ir; vbuhosp@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Anesthesiology and Critical Care Research Centre
Full name of responsible person
Dr. Mmohammad Haghighi
Position
Anesthesiologist, associate proffesor
Other areas of specialty/work
Street address
Namjoo street, Velaiat hospital
City
Rasht
Postal code
4193833697
Phone
+98 13 1321 0424
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mohaghighi@gums.ac.ir; vbuhosp@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Anesthesiology and Critical Care Research Centre
Full name of responsible person
Dr. Mohammad Haghighi
Position
Anesthesiologist, associate proffesor
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Street address
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Fax
+98 13 1324 5140
Email
mohaghighi@gums.ac.ir; Vbuhosp@gmail.com
Web page address

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