Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of the effect of thiopental sodium and propofol in electroconvulsive therapy on seizure duration and threshold changes based on electroencephalogram

Protocol summary

Study aim
Determination and comparison of the effects of thiopental sodium and propofol in electroconvulsive therapy on seizure duration and threshold changes

Design
A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 70 patients

Settings and conduct
In this randomized, double-blind clinical trial study, 70 eligible patients referred to Modares Hospital in Isfahan will be enrolled and randomly divided into two groups. Patients in the two groups will be prescribed succinylcholine with thiopental sodium or succinylcholine with propofol, respectively, before electroconvulsive therapy. In this study, the patient, data collector, and statistical analyst will be unaware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: candidates for ECT; over 18 years of age; not respond adequately to drug therapy; being at serious risk of suicide or harm to others if ECT was not administered; consent to participate in the study. Exclusion criteria: having a recent history of cardiovascular disease such as heart attack or congestive heart failure; having a brain tumor, cerebral aneurysm, or any increase in intracranial pressure; patients with uncontrolled heart failure; patients at risk of anesthesia (ASA level 4-5).

Intervention groups
First intervention group: In this group, patients receive 0.5 mg/kg of succinylcholine and 2 mg/kg of sodium thiopental before electroconvulsive therapy. Second intervention group: In this group, patients receive 0.5 mg/kg of succinylcholine and 1 mg/kg of propofol before electroconvulsive therapy.

Main outcome variables
Seizure time, Seizure threshold

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N71**
Registration date: **2025-09-06, 1404/06/15**
Registration timing: **prospective**

Last update: **2025-09-06, 1404/06/15**
Update count: **0**

Registration date
2025-09-06, 1404/06/15

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-22, 1404/06/31

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative study of the effect of thiopental sodium and propofol in electroconvulsive therapy on seizure duration and threshold changes based on electroencephalogram

Public title
The effect of thiopental sodium and propofol in electroconvulsive therapy on seizure duration

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for electroconvulsive therapy (such as patients with schizophrenia, major depression, bipolar disorder in the manic phase) Over the age of 18 Patients who have not responded adequately to medication or the individual/guardian is willing to undergo electroconvulsive therapy Patients who are at serious risk of suicide or harm to others if they do not receive electroconvulsive therapy Consent to participate in the study

Exclusion criteria:
Having a recent history of cardiovascular diseases such as myocardial infarction or congestive heart failure Having brain tumors, cerebral aneurysms or any increased intracranial pressure Patients with uncontrolled heart failure Patients at risk of anesthesia (ASA level 4-5)

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 70 eligible patients are randomly selected. For this, the letter A is written on 35 sheets, the letter B is written on 35 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to comply with the blinding conditions before electroconvulsive therapy, two drugs, thiopental sodium 2 mg/kg and propofol 1 mg/kg, are included in packages labeled A and B. Also, 0.5 mg/kg of succinylcholine is included in both packages. Thus, package A will contain succinylcholine and thiopental, and package B will contain succinylcholine and propofol. The interventionist will inject the drug without knowing the type of drug. Also, the patient will not be aware of the type of intervention. The data collector and statistician will not be aware of the type of therapeutic intervention in either group until after the data analysis is completed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Vice Chancellor for Research, Building No 4, Isfahan University Of Medical Sciences, Hezarjirib Street

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7346181746

Approval date
2025-02-12, 1403/11/24

Ethics committee reference number
IR.MUI.MED.REC.1403.461

Health conditions studied

1

Description of health condition studied
Candidate for electroconvulsive therapy

ICD-10 code
Y84.9

ICD-10 code description
Medical procedure, unspecified as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Seizure time

Timepoint
During the electroconvulsive therapy process

Method of measurement
Time in minutes

2

Description
Seizure threshold
Timepoint
During the electroconvulsive therapy process
Method of measurement
Based on electrocardiogram (ECG)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In this group, patients receive 0.5 mg/kg of succinylcholine and 2 mg/kg of sodium thiopental before electroconvulsive therapy.
Category
Treatment - Drugs

2

Description
Second intervention group: In this group, patients receive 0.5 mg/kg of succinylcholine and 1 mg/kg of propofol before electroconvulsive therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available