

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of effect of Succinylcholine and Cisatracurium in seizure time in electroconvulsive therapy in children with psychologic disease

#### Protocol summary

##### Summary

The goal of the article is comparison of seizure time in electro convulsive therapy (ECT) using Cisatracurium and Succinylcholine. It is a clinical trial study in phase 3, double blind randomized (Randomization with table of randomized number), without placebo control and mono-central. The study population consists of children with psychological diseases and total sample size is 60 which is divided into two groups of 30 people entitled A and B. Three drugs, Cisatracurium 50 µg/kg, Succinylcholine 0.5 mg/kg and Sodium thiopental 2mg/kg are grouped into two packages of A and B. Package A consists of Cisatracurium and Sodium thiopental and package B consists of Succinylcholine and Sodium thiopental. The patients are divided into two groups receiving package A and B respectively. After taking informed consent from patients, an appropriate intravenous (IV) line will be taken and ECG and pulse oximeter and noninvasive blood pressure devices will be attached to the patients. ECT device will be attached bi-temporally and then time of seizure and tonic and clonic phases will be measured by chronometer. Moreover oxygen saturation and patient's vital signs will be measured before, during and after receiving the drugs. Main inclusion criterion is patients under 25 who are candidates to ECT and main exclusion criteria are patients with seizure time more than 90 seconds and less than 20 seconds and persistent medical problems.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081229310N1**

Registration date: **2016-09-21, 1395/06/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-21, 1395/06/31

##### Registrant information

###### Name

Behzad Nazemroaya

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-08-31, 1395/06/10

##### Expected recruitment end date

2016-10-31, 1395/08/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effect of Succinylcholine and Cisatracurium in seizure time in electroconvulsive therapy in children with psychologic disease

##### Public title

Comparison of effect of Succinylcholine and Cisatracurium on seizure time in electroconvulsive therapy

##### Purpose

Other

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients under 25 years who are candidates for electroconvulsive therapy (ECT). Exclusion criteria: persistent medical problems, seizure more than 90 seconds and less than 20 seconds, need to intubation, severe allergy, past history of seizure and epilepsy, addiction to alcohol and drugs.

### **Age**

To **25 years** old

### **Gender**

Both

### **Phase**

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**

Not used

### **Assignment**

Parallel

### **Other design features**

Randomization will be done with table of randomized numbers.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

##### **Street address**

Isfahan University of Medical Sciences, Hezar jarib street, Azadi square, Isfahan

##### **City**

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##### **Postal code**

8174673461

#### **Approval date**

2016-06-20, 1395/03/31

#### **Ethics committee reference number**

IR.MUI.REC.1395.3.239

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Attention deficit-hyperactivity disorder(ADHD)

#### **ICD-10 code**

F90

#### **ICD-10 code description**

Disturbance of activity and attention

### **2**

#### **Description of health condition studied**

anorexia nervosa

#### **ICD-10 code**

F50

#### **ICD-10 code description**

Anorexia nervosa

### **3**

#### **Description of health condition studied**

mental retard

#### **ICD-10 code**

F70,F71,F7

#### **ICD-10 code description**

Mental retardation

### **4**

#### **Description of health condition studied**

schizophrenia

#### **ICD-10 code**

F20

#### **ICD-10 code description**

schizophrenia

### **5**

#### **Description of health condition studied**

depression

#### **ICD-10 code**

F32

#### **ICD-10 code description**

Depressive episode

### **6**

#### **Description of health condition studied**

bipolar disorder

#### **ICD-10 code**

F30

#### **ICD-10 code description**

manic episode

### **7**

#### **Description of health condition studied**

psychosis

#### **ICD-10 code**

F23

#### **ICD-10 code description**

acute and transient psychotic disorders

### **8**

#### **Description of health condition studied**

conduct disorder

**ICD-10 code**

F91

**ICD-10 code description**

conduct disorder

**9****Description of health condition studied**

Obsessive-compulsive disorder(OCD)

**ICD-10 code**

F42

**ICD-10 code description**

obsessive compulsive disorder

**10****Description of health condition studied**

anxiety disorder

**ICD-10 code**

F41

**ICD-10 code description**

Other anxiety disorders

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

duration of seizure

**Timepoint**

after intervention

**Method of measurement**

in seconds using a chronometer

**2****Description**

duration of tonic phase

**Timepoint**

after intervention

**Method of measurement**

in seconds using a chronometer

**3****Description**

duration of clonic phase

**Timepoint**

after intervention

**Method of measurement**

in seconds using a chronometer

**4****Description**

Blood Pressure

**Timepoint**

1, 5 and 10 seconds after the shock

**Method of measurement**

mmhg with Manometer

**5****Description**

Pulse

**Timepoint**

1, 5 and 10 seconds after the shock

**Method of measurement**

Beat per minute with Pulse Oximeter

**6****Description**

Beat per minute with Pulse Oximeter

**Timepoint**

O2 saturation

**Method of measurement**

Percent with Pulse Oximeter

**7****Description**

Recovery Duration

**Timepoint**

From the end of seizure to full consciousness

**Method of measurement**

Minute with Timer

**8****Description**

Back to Breathe Spontaneously

**Timepoint**

From the end of seizure to respiration

**Method of measurement**

Second with Timer

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

Cough

**Timepoint**

After recovery

**Method of measurement**

Ask the patient

**2****Description**

Nausea and Vomiting

**Timepoint**

After recovery

**Method of measurement**

Ask the patient

**3****Description**

Headache

**Timepoint**

After recovery

**Method of measurement**

Ask the patient

#### 4

##### **Description**

Muscle Pain

##### **Timepoint**

After recovery

##### **Method of measurement**

Ask the patient

#### 5

##### **Description**

Laryngospasm

##### **Timepoint**

After recovery

##### **Method of measurement**

Evaluation of patient such as breathing and o2 sat

## **Intervention groups**

#### 1

##### **Description**

Group B (the control group): After taking informed consent from patients, an appropriate intravenous (IV) line will be taken and ECG and pulse oximeter and noninvasive blood pressure devices will be attached to the patients. Pharmaceutical package B which consists of 0.5 mg/kg of Succinylcholine and 2mg/kg of Sodium thiopental will be injected through IV line. Then ECT will be attached bi-temporally and shocks will be applied to the patient and then time of tonic and clonic phases and also time of seizure will be measured by chronometer.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Group A (intervention group): After taking informed consent from patients, an appropriate intravenous (IV) line will be taken and ECG and pulse oximeter and noninvasive blood pressure devices will be attached to the patients. Pharmaceutical package A which consists of 50µg/kg of Cisatracurium and 2mg/kg of Sodium thiopental will be injected through IV line. Then ECT will be attached bi-temporally to the patient and shocks will be applied to the patient. Then time of tonic and clonic phases and also duration of seizure will be measured by chronometer

##### **Category**

Treatment - Drugs

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Alzahara hospital's pediatric psychiatry ward 's

electroconvulsive therapy center

##### **Full name of responsible person**

Behzad Nazemroaya ,Assistant Professor,  
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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice chancellor for research Isfahan University of  
Medical Sciences

###### **Full name of responsible person**

Dr mehdi nourbakhsh

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###### **City**

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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 Isfahan 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**

Isfahan university of medical sciences

###### **Full name of responsible person**

Forough Mirzakhani Hafshejani

###### **Position**

Medical student/ Intern

###### **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*