

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### **A comparative study of the effect of adding Dexmedetomidin on variation in heart rate and blood pressure after the anesthesia by Thiopental sodium in children's Electroconvulsive therapy(ECT)**

#### **Protocol summary**

##### **Study aim**

The effect of adding Dexmedetomidin on variation in heart rate and blood pressure after anesthesia with Thiopental sodium in electroconvulsive therapy

##### **Design**

This study was conducted in parallel ,double-blind,randomized,60 patients who were in the phase 3 trial were designed.

##### **Settings and conduct**

Patients who are referred to pediatric psychology ward of al-Zahra hospital and are candidate of receiving electroshock therapy are randomly divided into two groups including interventional group who receives 0/2 mcg/kg Dexmedetomidin and control group who receives normal saline. Then the heart rate and blood pressure of each patient is detected. Participants, care provider, outcome assessor ,are not aware of the drug type and the investigator deciphers the codes after data analysis.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria:1)Patients candidate receiving electroconvulsive therapy 2)Patients younger than 25 years old 3)Patients with American Society of Anesthesiology physical status class 1,2 (ASA1 ,ASA2) 4)Patients with satisfaction to participate in study  
Exclusion criteria:1)Patients with allergies to the drugs studied

##### **Intervention groups**

Initially, personal consent is obtained from parents of patients. Then the patient is placed on the operating bed and standard monitoring devices including pulse oximetry, capnography, and electrocardiogram are attached. Then Dexmedetomidin 0/2 mcg/kg is injected to interventional group .In control group patients are injected from syringe filled with normal saline.

##### **Main outcome variables**

Blood pressure and heart rate

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20160307026950N13**

Registration date: **2019-06-19, 1398/03/29**

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

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

##### **Registration date**

2019-06-19, 1398/03/29

##### **Registrant information**

##### **Name**

Behzad Nazemroaya

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

Isfahan University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 3212 3543

##### **Email address**

behzad\_nazem@med.mui.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2018-03-21, 1397/01/01

##### **Expected recruitment end date**

2019-09-22, 1398/06/31

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

### Scientific title

A comparative study of the effect of adding Dexmedetomidin on variation in heart rate and blood pressure after the anesthesia by Thiopental sodium in children's Electroconvulsive therapy(ECT)

### Public title

THE effect of adding Dexmedetomidine on variation in heart rate and blood pressure after anesthesia with Thiopental sodium in electroconvulsive therapy (Ect)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients younger than 25 years old Patients with American society of anesthesiology physical status class 1,2 (ASA 1,ASA2) Patients candidate receiving electroconvulsive therapy Patients with satisfaction to participate in study

#### Exclusion criteria:

Patients with allergies to the drugs studied

### Age

To 25 years old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization method: Block Randomization unit: Individual Randomization tool: Random Allocation software Patients are randomly assigned to intervention and control groups using the Random Allocation computer software

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The drugs are prepared in one form and in the same volume in the syringe by the researcher and the hemodynamic changes are monitored and recorded so the attending and the clinical caregiver and the evaluator and data analyser do not understand the type of medication and the investigator deciphers the codes after dara analysis.

### 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

Hezar jarib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2018-02-09, 1396/11/20

#### Ethics committee reference number

IR.Mui.REC.1396.3.791

## Health conditions studied

### 1

#### Description of health condition studied

Blood pressure

#### ICD-10 code

R03.0

#### ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

### 2

#### Description of health condition studied

Heart rate

#### ICD-10 code

R00.0

#### ICD-10 code description

Tachycardia, unspecified

## Primary outcomes

### 1

#### Description

Heart rate changes

#### Timepoint

Before the intervention,during the seizure ,1,5,10 minutes after end of seizure

#### Method of measurement

Heart monitoring

### 2

#### Description

Mean arterial pressure

### **Timepoint**

Before the intervention,during seizure,1,5,10 minutes after end of seizure

### **Method of measurement**

Non invasive blood pressure monitor

### **3**

#### **Description**

Systolic blood pressure

#### **Timepoint**

Before the intervention , during seizure , 1,5,10 minutes after end of seizure

#### **Method of measurement**

Non invasive blood pressure monitor

### **4**

#### **Description**

Diastolic blood pressure

#### **Timepoint**

Before the intervention , during seizure , 1,5,10 minutes after end of seizure

#### **Method of measurement**

Non invasive blood pressure monitor

### **5**

#### **Description**

Oxygen saturation

#### **Timepoint**

Before intervention ,during seizure , 1,5,10 minutes after end of seizure

#### **Method of measurement**

Percent with pulse oximeter

### **6**

#### **Description**

Duration of seizure

#### **Timepoint**

After intervention

#### **Method of measurement**

In second using a chornometer

### **7**

#### **Description**

Recovery time

#### **Timepoint**

From the end of seizure to full consciousness

#### **Method of measurement**

Minute with using a chornometer

### **8**

#### **Description**

Back up self breathing time

#### **Timepoint**

From the end of seizure until back up self breathing

#### **Method of measurement**

Seconds with using a chronometer

## **Secondary outcomes**

### **1**

#### **Description**

Nausea and Vomiting

#### **Timepoint**

After end of the seizure

#### **Method of measurement**

Questionnaire

### **2**

#### **Description**

Laryngospasm

#### **Timepoint**

After end of the seizure

#### **Method of measurement**

Evaluation of respiration and oxygen saturation

### **3**

#### **Description**

Headache

#### **Timepoint**

After the end of seizure

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Initially,personal consent is obtained from the parents of patients.Then the patient is placed on the operating bed and standard monitoring devices including :pulsoximetry ,capnography and electrocardiogram are attached.In this group Dexmedetomidin 0/2 mcg/kg is injected.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Initially,personal consent is obtained from the parents of patients.Then the patient is placed on the operating bed and standard monitoring devices including :pulsoximetry ,capnography and electrocardiogram are attached. In this group patients are injected from a syringe filled with Normal saline.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Al-zahra hospital

**Full name of responsible person**

Behzad Nazemroaya

**Street address**

Soffeh boulevard, Shahid Keshvari highway

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

behzad\_nazem@med.mui.ac.ir

**Position**

Medical student/Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 112, Negin-abshar Building ,Rezvan Alley , First  
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**Email**

mahtabnourbakhsh@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghyegh Haghjoo

**Street address**

Hezarjarib street

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Isfahan

**Province**

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**Phone**

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research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahtab Nourbakhsh

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Behzad Nazemroaya

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahtab Nourbakhsh

**Position**

Medical student /Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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