Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pressue 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 salin.Then the heart rate and blood pressure of each patient is detected. Participants,care provider, outcome assessor ,are not aware of the drugtype 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 pulsoximetry,capnography,and electrocardiogram are attache.Then Dexmetedomidin 0/2 mcg/kg is injected to interventional group .In control group patients are injected from syringe filled with normal salin.

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
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Iran (Islamic Republic of)
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+98 31 3212 3543
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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
Isfehan
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 siezure
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
N on 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 salin.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital

Full name of responsible person
Behzad Nazemroaya
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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?
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
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Position
Medical student/Intern
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Person responsible for updating data

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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