Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of pre-operative administration of Dexmedetomidine on pulse rate and blood pressure with placebo following the administration of Ketamine for electroconvulsive therapy of pediatric

Protocol summary

Study aim

Comparison of pre-operative administration of Dexmedetomidine on pulse rate and blood pressure with placebo following the administration of Ketamine for electroconvulsive therapy

Design

This study was conducted in parallel, double-blind, randomized, 64 patients who were in the Phase 3 trial were designed.

Settings and conduct

Patients who are referred to pediatric phychology ward of al-Zahra hospital and are candidate of receiving electroshock therapy are randomly divided into two groups including interventional group who recieves 0.1 mcg/kg dexmedetomidine 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 older than 6 yeras old and younger than 25 years old 3)Patients with American society of anesthesiology physical status class 1,2 (ASAI,II) Exclusion criteria: 1)Addiction to drugs and alcohol 2)cardio-pulmonary diseases 3)Beta blockers and narcotics and high blood pressure drugs consumption 4)Drug allergy

Intervention groups

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.then Dexmedetomidine 0.1 mcg/kg is injected to interventional group. In control group patients are injected from a 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: **IRCT20160307026950N10**
Registration date: **2019-04-24, 1398/02/04**
Registration timing: **retrospective**

Last update: **2019-04-24, 1398/02/04**
Update count: **0**

Registration date

2019-04-24, 1398/02/04

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of pre-operative administration of Dexmedetomidine on pulse rate and blood pressure with placebo following the administration of Ketamine for electroconvulsive therapy of pediatric

Public title
The effect of pre-operative administration of Dexmedetomidine on pulse rate and blood pressure following the administration of Ketamine for electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidate receiving electroconvulsive therapy Patients older than 6 yeras old and younger than 25 years old Patients with American society of anesthesiology physical status class 1,2 (ASAI,II)
Exclusion criteria:
Addiction to drugs and alcohol History of cardio-pulmonary diseases History of consumption of Beta blockers and narcotics and high blood pressure drugs Drug allergy
Age
From **6 years** old 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: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to intervention and control groups ttusing the Random Allocation computer software
Blinding (investigator's opinion)
Double blinded
Blinding description
The dug and placebo are prepared in one form and in the form of a 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 data analysis.
Placebo
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
2017-05-28, 1396/03/07
Ethics committee reference number
IR.MUI.REC.1396.3.792

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, 1 , 5, 10 minutes after end of seizure and then the discharge time of recovery
Method of measurement
Heart monitoring

2

Description
Mean arterial blood pressure
Timepoint
Before the intervention, 1 , 5, 10 minutes after end of seizure and then the discharge time of recovery
Method of measurement
Non invasive blood pressure monitor

3

Description
Duration of seizure
Timepoint
After intervention
Method of measurement
In seconds using a chornometer

4

Description
oxygen saturation
Timepoint
Before the intervention, 1,5,10 minutes after end of seizure and then the discharge time of recovery
Method of measurement
Percent with pulse oximeter

5

Description
recovery time
Timepoint
From the end of seizure to full consciousness
Method of measurement
Minute with using a chronometer

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
After end of the siezure
Method of measurement
Questionnaire

2

Description
laryngospasm
Timepoint
After end of the siezure
Method of measurement
Evaluation of respiration and oxygen saturation

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 Dexmedetomidine 0.1 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
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Sponsors / Funding sources

1

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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
Full name of responsible person
Marzieh Babhadiashar
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