Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The investigation of the effect of adding Dexmedetomidine to Propofol on changes in heart rate and blood pressure in pediatric Electroconvulsive therapy

Protocol summary

Study aim

Evaluation of the effect of adding Dexmedetomidine to Propofol in pediatric Electroconvulsive therapy

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Lottery was used for randomization.

Settings and conduct

This study is a randomized, double-blind clinical trial that will be performed on children who are candidates for electroconvulsive therapy at Al-Zahra Hospital in Isfahan. Before the arrival of patients, their parents will be informed about the study and if they are satisfied, they will be prepared and monitored for the intervention. Patients are randomly distributed in two groups and each group receives the relevant intervention after propofol injection. The clinical caregiver is different from the person injecting the drug and is unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 4 to 16 years old, ECT candidate, ASA class I and II anesthesia Exclusion criteria: History of seizures, Heart failure, Kidney failure, Liver failure, Respiratory failure, History of allergy to the studied drugs, Addiction to psychotropic substances, History of egg allergy

Intervention groups

Intervention group A: In this group, after injecting propofol, patients are injected with 0.5 mg of dexmedetomidine per kg of body weight. Intervention group B: In this group, after injection of propofol, patients are injected with 0.5 ml of normal saline.

Main outcome variables

Heart rate changes; Changes in blood pressure

General information

Reason for update

Acronym

ETC نام اختصاری Electro Convulsive Therapy میباشد.

IRCT registration information

IRCT registration number: **IRCT20160307026950N29**
Registration date: **2020-12-21, 1399/10/01**
Registration timing: **prospective**

Last update: **2020-12-21, 1399/10/01**
Update count: **0**

Registration date

2020-12-21, 1399/10/01

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

2020-12-30, 1399/10/10

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The investigation of the effect of adding Dexmedetomidine to Propofol on changes in heart rate and blood pressure in pediatric Electroconvulsive therapy

Public title
The effect of Dexmedetomidine in pediatric Electroconvulsive therapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children 4 to 16 years Candidate for ETC ASA Class I & II

Exclusion criteria:
Patients with a history of seizures, Heart failure, Kidney failure, Liver failure, Respiratory failure History of allergy to the studied drugs Addiction to psychotropic substances History of egg allergy

Age
From **4 years** old to **16 years** old

Gender
Both

Phase
3

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
Randomization is done by block method; In this way, the first patient enters one of the groups by drawing lots, then from the second patient, the patients enter the two groups one by one, so that their number in each group reaches 35 people.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study; As the clinical caregiver is different from the person injecting the drug and is unaware of the type of intervention, patients are also unaware of the type of intervention applied and are therefore blind.

Placebo
Used

Assignment
Parallel

Other design features
In this study, awareness and consent of patients' parents is obtained.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences Committe for Ethics in Biomedical Research

Street address
Hezar Jarib St

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-03-01, 1398/12/11

Ethics committee reference number
IR.MUI.MED.REC.1398.638

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

Timepoint
Before drug injection and 1, 2, 3, 5 and 10 minutes after anesthesia

Method of measurement
ECG

2

Description
Blood Pressure

Timepoint
Before drug injection and 1, 2, 3, 5 and 10 minutes after anesthesia
Method of measurement
Manometer

Secondary outcomes

1

Description
Duration of anesthesia
Timepoint
From the beginning of anesthesia to the end of recovery
Method of measurement
Timer

2

Description
Duration of seizures
Timepoint
From the moment of the beginning of contractions until the time of relaxation
Method of measurement
Timer

Intervention groups

1

Description
Intervention group A: Patients in this group after lying on the bed and monitoring connection with 0.5 mg per kg body weight SuccinylCholine, 2 mg per kg body weight Thiopental and 1 mg Propofol per kg body weight and then 0.5 mg / kg Dexmedetomidine is anesthetized and Electroconvulsive therapy is initiated. Patients are recorded during ECT until the end of monitor recovery and changes in vital signs.
Category
Prevention

2

Description
Control group B: Patients in this group after lying on the bed and monitoring connection with 0.5 mg per kg body weight Succinylcholine, 2 mg per kg body weight Thiopental and 1 mg Propofol per kg body weight and then 0.5 ml of normal saline is anesthetized and Electroconvulsive therapy is initiated. Patients are recorded during ECT until the end of monitor recovery and changes in vital signs.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad Nazemoroaya
Street address
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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
Vice Chancellor for Research, 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

Esfahan University of Medical Sciences

Full name of responsible person
Dorna Masaely

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Latest degree
Specialist

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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