

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 میباشد نام اختصاری Electro Convulsive Therapy

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

Country

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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

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Isfahan

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

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Soffeh boulevard, Shahid Keshvari highway

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

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Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Professor assistant of Anesthesia and Intensive
care intensive care

Latest degree

Specialist

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Anesthesiology

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Person responsible for updating data

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Bachelor

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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