Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

A comparative study of heart rate and blood pressure changes during and after electroconvulsive therapy followed by two different doses of labetalol in two groups of patients

Protocol summary

Study aim
A comparative study of heart rate and bloodpressure changes during and after elecrtoconvulsive therapy followed by two different doses of labetalol in two groups of patients

Design
This study will be conducted in parallel, double-blind, randomized, 40 people who are in the Phase 3 trial.

Settings and conduct
Patients are referred to pediatric psychology ward of al-Zahra hospital. The patients are randomly divided into two groups.For all intervention groups, informed consent is obtained from the parents of patients. Then an appropriate peripheral vein is taken from the patients and the blood pressure and electrocardiography and pulse oximetry devices are connected to the patients.group A recieve 0.2 mg/kg labetalol and group B recieve 0.4 mg/kg labetalol.the haert rate and blood pressure of each patient is detected. The Participants, Care provider, Outcome assessor, and Data analyser are not aware of the drug type and the investigator deciphers the codes after data analysis.

Participants/Inclusion and exclusion criteria
inclusion criteria : patients candidates receiving electroconvulsive therapy Subjects older than 6 years old and younger than 25 years old American Society of Anesthesiology physical status class 1,2 (ASAI, II) Exclusion criteria: subjects with severe cardiovascular disease, kidney disease, Liver disease, respiratory disease, drugs Allergy

Intervention groups
All patients recieve 0.5 mg/kg succinylcholine and 2mg/kg thiopental sodium. Intervention group A recieves 0.2 mg/kg labetalol and Intervention group B recieves 0.4mg/kg labetalol.

Main outcome variables
blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N11**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **retrospective**

Last update: **2019-05-27, 1398/03/06**
Update count: **0**

Registration date
2019-05-27, 1398/03/06

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
A comparative study of heart rate and blood pressure changes during and after electroconvulsive therapy followed by two different doses of labetalol in two groups of patients

Public title
Effects of two different doses of labetalol on electroconvulsive therapy in two groups of patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients candidates receiving electroconvulsive therapy Subjects older than 6 yeras old and younger than 25 years old American society of anesthesiology physical status class 1,2 (ASAI,II)

Exclusion criteria:
Severe cardiovascular disease Severe respiratory disease Severe kidney disease Severe Liver disease Drugs Allergy

Age
From **6 years** old to **25 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to two groups A, B using the Random Allocation computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
All drugs are 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 do not understand the type of medication.

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
2017-05-27, 1396/03/06

Ethics committee reference number
IR.MUI.REC.1396.3.677

Health conditions studied

1

Description of health condition studied
Heart rate and blood pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Heart rate changes

Timepoint
Before the intervention, 1 , 5, 10 minutes after intervention and then After The discharge time of recovery

Method of measurement
Pulse oximetry device

2

Description
Mean arterial blood pressure

Timepoint
Before the intervention,1 , 5, 10 minutes after intervention and then After The discharge time of recovery

Method of measurement
Non invasive blood pressure

3

Description
Oxygen saturation

Timepoint
Before the intervention, 1 , 5, 10 minutes after intervention and then After The discharge time of recovery

Method of measurement
Pulse oximetry device

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
Questionnaire

3

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

4

Description
Recovery duration
Timepoint
From the end of seizure to full consciousness
Method of measurement
Minute with using a chornometer

Intervention groups

1

Description
Intervention group A: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached.all patients recieve 0.5 mg/kg succinylcholine and 2mg/kg thiopental sodium. In this group 0.2 mg/kg labetalol is injected.
Category
Treatment - Drugs

2

Description
Intervention group B: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached.all patients recieve 0.5 mg/kg succinylcholine and 2mg/kg thiopental sodium. In this group 0.4 mg/kg labetalol is injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Behzad Nazemroaya
Street address
Soffeh boulevard, Shahid Kesari highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghyegh Haghjoo
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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

Negar Rezaei

Position

Medical student/ Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Negar rezaie joochi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

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