Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effectiveness of low-dose Esmolol and Labetalol on changes in heart rate and blood pressure in patients treated with electroshock (ECT)

Protocol summary

Study aim
Comparison of the effect of prophylactic injection of low doses of esmolol and labetalol on changes in heart rate and blood pressure in electroshock therapy (ECT)

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. Random Allocation software is used for randomization

Settings and conduct
This is a double-blind clinical trial study in which the target population is ETC candidate patients at Al-Zahra Hospital in Isfahan. Patients are randomly assigned to three groups: C, B, and A, and each group is randomly injected into one of the three intervention groups. The patient's vital signs are checked and recorded before, during, and after ECT. The injector, the clinical caregiver and the patient are unaware of the injected intervention and are blind.

Participants/Inclusion and exclusion criteria
ECT candidate patients between the ages of 13 and 19 with class I and II ASA will be included in the study if they do not have a specific underlying problem.

Intervention groups
A group: 0.2 mg/kg Labetalol B group: 0.5 mg/kg Esmolol C group: Normal saline as pelacebo

Main outcome variables
Heart Rate; Blood Pressure

General information

Reason for update

Acronym
ECT

IRCT registration information
IRCT registration number: **IRCT20160307026950N19**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **prospective**
Last update: **2022-07-12, 1401/04/21**
Update count: **1**

Registration date
2020-06-02, 1399/03/13

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of low-dose Esmolol and Labetalol on changes in heart rate and blood pressure in patients treated with electroshock (ECT)

Public title
Esmolol and Labetalol in ECT

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for electroshock therapy Range of 13 to 19 years ASA class I and II The patient's consent to participate in the study

Exclusion criteria:

Contraindications to the use of Esmolol and Labetalol Previous consumption of beta-blockers Sensitivity to Esmolal and labetalol Asthma and drug allergies History of severe cardiovascular disease, chronic respiratory disease, kidney disease, and liver disease

Age

From **13 years** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple way and patients are distributed in intervention and control groups using Random Allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs and placebo are packaged in the same form with the same volume and coded and are randomly distributed among patients, so the participant and the clinical and evaluator are not aware of the type of drug.

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

2020-05-01, 1399/02/12

Ethics committee reference number

IR.MUI.MED.REC.1399.105

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 prescribing Esmolal, labetalol, and normal saline, before prescribing anesthesia, just before the ECT, during the shock, 1, 3, 5, 10, and 20 minutes after the shock.

Method of measurement

ECG monitoring and Pulse Oximeter

2

Description

Systolic Blood Pressure

Timepoint

Before prescribing Esmolol, labetalol, and normal saline, before prescribing anesthesia, just before the ECT, during the shock, 1, 3, 5, 10, and 20 minutes after the shock.

Method of measurement

Non-invasive blood pressure measurement

3

Description

Diastolic Blood Pressure

Timepoint

Before prescribing Esmolol, labetalol, and normal saline, before prescribing anesthesia, just before the ECT, during the shock, 1, 3, 5, 10, and 20 minutes after the shock.

Method of measurement

Non-invasive blood pressure measurement

4

Description

Mean Arterial Pressure

Timepoint

Before prescribing Esmolol, labetalol, and normal saline, before prescribing anesthesia, just before the ECT, during the shock, 1, 3, 5, 10, and 20 minutes after the shock.

Method of measurement

Non-invasive blood pressure measurement

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

Before prescribing Esmolol, labetalol, and normal saline, before prescribing anesthesia, just before the ECT, during the shock, 1, 3, 5, 10, and 20 minutes after the shock.

Method of measurement

Pulse oximeter

2

Description

The duration of the seizure

Timepoint

Beginning to the end of the seizure

Method of measurement

Chronometer

3

Description

The duration of anesthesia

Timepoint

Beginning to the end of the anesthesia

Method of measurement

Chronometer

4

Description

Recovery time

Timepoint

From the end of anesthesia to full awakening

Method of measurement

Watch

5

Description

Nausea and Vomiting

Timepoint

During the stay in the recovery

Method of measurement

Ask the patient about this complication

6

Description

Headache

Timepoint

During the stay in the recovery

Method of measurement

Asking from the patient

7

Description

Larangospasm

Timepoint

During the stay in the recovery

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention Group A; Labethalol is administered at a dose of 0.2 mg per kg body weight prior to anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group B; Esmolol is injected 0.5 mg per kilogram of body weight prior to anesthesia.

Category

Treatment - Drugs

3

Description

Control group C; Normal saline is injected into the patient as a placebo before injecting the anesthetic.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazemoroaya

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Sponsors / Funding sources

1

Sponsor
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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

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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