Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of efficacy and safety of two muscle relaxants cisatracurium and succinylcholine in Electroconvulsive therapy; A randomized, single-blind clinical trial study

Protocol summary

Study aim

Comparing the efficacy and safety of two muscle relaxants, cisatracurium and succinylcholine in electroconvulsive therapy

Design

A single-blinded and randomized clinical trial, phase 3, without control group, with parallel groups design of 62 patients

Settings and conduct

This study will be done as a clinical trial at Shafa hospital in Rasht. Informed consent will be taken from patients and if not possible to communicate, it will be obtained from the patient's legal companion. The procedure is the same for both groups. A fasting period of eight hours will be observed for all patients. Standard monitoring will be performed upon the patient's arrival at the ECT ward. After establishing a suitable intravenous line, induction of anesthesia will be done. After confirming proper ventilation with mask and no response to verbal commands, relaxing drugs will be injected and the patient will get electroshock therapy.According to returning of spontaneous breathing and level of consciousness, the patient will be monitored for 15 to 20 minutes in the recovery department and then discharged. In this study, only the patient is blind, and the evaluator (resident of anesthesiology) and the responsible anesthesiologist are aware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 years and older, ASA I, II, Normal body mass index, No criteria for difficult mask ventilation, No contraindication for cisatracurium and succinylcholine.Exclusion criteria: myasthenia gravis, History of malignant hyperthermia, History of burns, Kidney failure, Guillain-Barré syndrome, Dangerous arrhythmias.

Intervention groups

First group: induction of anesthesia with Propofol 1 mg per kg and succinylcholine 0.5 mg per kg.Second group: Propofol 1 mg per kg and Cis atracurium 0.1 mg per kg are prescribed.

Main outcome variables

Seizure duration, time of returning of the effective breaths of the patient time of recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006280N14**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **prospective**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

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Mohammad Haghighi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date
2023-10-23, 1402/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of efficacy and safety of two muscle relaxants cisatracurium and succinylcholine in Electroconvulsive therapy; A randomized, single-blind clinical trial study

Public title
Efficacy and safety of two muscle relaxants cisatracurium and succinylcholine in Electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 years and older ASA I,II Normal body mass index No criteria for difficult mask ventilation No contraindication for cisatracurium and succinylcholine
Exclusion criteria:
myasthenia gravis History of malignant hyperthermia History of burns Kidney failure Guillain-Barré syndrome Any nerve denervation Dangerous arrhythmias
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups by an anesthesia technician who does not participate in the project, using four random blocks created by the computer (Win Pepi 11.65 software). This is done through a list of eligible patients who have given informed consent. They will be assigned to one of the two groups receiving succinylcholine or cisatracurium by a sequence of randomization blocks in a 1: 1 ratio. The output of the software consists of letters and numbers. The letters A and B indicate the under-study treatments (succinylcholine and cisatracurium) and the indicated numbers indicate the patients who will be assigned to the treatments consecutively.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded study. In this way, the patient is blind, but due to the nature of the relaxant drugs and their different pharmacodynamics, including obvious and generalized fasciculation of succinylcholine, the evaluator (resident of anesthesiology) who fills out the checklist is aware of the treatment groups. The responsible anesthesiologist present in the shock department is also aware of the groups in order to perform the necessary intervention in case of complications (bradycardia, master spasm, ECG changes in favor of hyperkalemia, hemodynamic changes, and arterial blood oxygenation).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Comeetee of Guilan University of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
City
Rasht
Province
Guilan
Postal code
4193713189
Approval date
2023-05-03, 1402/02/13
Ethics committee reference number
IR.GUMS.REC.1402.078

Health conditions studied

1

Description of health condition studied
Investigation of using cisatracurium instead of succinylcholine for anesthesia in electroshock therapy in cases that there is a contraindication for succinylcholine
ICD-10 code
T88.5
ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
Seizure duration
Timepoint

Momentary monitoring of colonic movements in the organ from the beginning of the seizure

Method of measurement

chronometer

2

Description

Time of returning of the effective breaths of the patient

Timepoint

Momentary monitoring from the beginning of the seizure

Method of measurement

chronometer

3

Description

Time of recovery

Timepoint

recovery time

Method of measurement

Observation

4

Description

Patient discharge from recovery

Timepoint

Momentary monitoring to score 9 or 10

Method of measurement

Aldret score

Secondary outcomes

1

Description

Mean arterial blood pressure (MAP)

Timepoint

Before injection, 1 minute after seizure and 15 minutes after induction of anesthesia

Method of measurement

Blood pressure measurement

2

Description

Heart rate (pulse/ minute)

Timepoint

Before injection, 1 minute after seizure and 15 minutes after induction of anesthesia

Method of measurement

Heart rate monitor

Intervention groups

1

Description

first intervention group: Before receiving anesthesia and electroshock therapy, standard monitoring of non-invasive blood pressure, pulse oximetry, electrocardiogram, and end-tidal carbon dioxide will be established and atropine 0.5 milligrams will be prescribed. After establishing a proper intravenous cateter size 20-18, induction of anesthesia with propofol 1 miligrams/kilograms and cisatracurium 0.1 miligrams/kilograms will be prescribed.

Category

Treatment - Drugs

2

Description

Second intervention group: After establishing a proper venous catheter, induction of anesthesia with propel 1 milligrams/kilograms and succinylcholine 0.5 milligrams/kilograms will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Dr.mohammad haghighi

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Shahid beheshti Kamarbandi, Khordad 15 street, Heshmat crossroads

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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
Rasht 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
Rasht University of Medical Sciences
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Mohammad Haghighi
Position
Full Professor
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Other areas of specialty/work
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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