

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Name

Mohammad Haghghi

Name of organization / entity

Guilan University of Medical Sciences

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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

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget 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

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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 milligrams/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 haghghi

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Shahid beheshti Kamarbandi, Khordad 15 street, Heshmat crossroads

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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?**

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

Full name of responsible person

Mohammad Haghighi

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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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