

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of cardiovascular changes and serum potassium levels in the use of succinylcholine and cisatracurium drugs in electroshock therapy

Protocol summary

Study aim

Comparison of cardiovascular changes and serum potassium levels in the use of succinylcholine and cisatracurium drugs in electroshock therapy.

Design

This study was a cross-over, double-blind, randomized, 45 patients who were in the Phase 3 trial were designed.

Settings and conduct

This is a double-blind clinical trial that was performed on 45 patients with electroshock candidate who were referred to Al-Zahra Hospital. patients were randomly assigned to two groups and Then they were placed in two Sequence and two Period with packages (a) and (b) under the electroshock. The person who prescribes the drug and the person who registers the vital signs are different and are unaware of the contents of the packages.. Cardiac monitoring includes electrocardiogram, heart rate, pulse oximetry and noninvasive blood pressure for all patients is done. Heart rate Median arterial blood pressure Diastolic and systolic blood pressure Hemoglobin saturation of oxygen is measured in 4 times.

Participants/Inclusion and exclusion criteria

The criteria for entering this study include those under the age of 18 years and the physical status of Classes one and two. Also, non-compliance criteria include high obesity , history of asthma, allergies, heart attacks , stroke , fibrillation and flutter.

Intervention groups

The method was done so that patients were randomly assigned to two groups and Then they were placed in two Sequence and two Period with packages (a) and (b) under the electroshock. The package (a) contains 1.5 mg of ketamine per kg of body weight and 0.5 mg of succinylcholine per kg of body weight Package (b) contains 1.5 mg of ketamine per kg of body weight and 50 µg of cisatracurium per kg of body weight

Main outcome variables

Serum potassium level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N14**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **retrospective**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

Email address

behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

2019-03-06, 1397/12/15

Actual recruitment end date

2019-04-14, 1398/01/25

Trial completion date

2019-05-05, 1398/02/15

Scientific title

Comparison of cardiovascular changes and serum potassium levels in the use of succinylcholine and cisatracurium drugs in electroshock therapy

Public title

The effect of two drugs succinylcholine and cisatracurium in electroshock therapy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People under the age of 18 American Society of Anesthesiology physical status class 1,2

Exclusion criteria:

Obesity (index is equal to or greater than 30 History of asthma Allergy Myocardial infarction in the last 6 months Stroke in the last 6 weeks Fibrillation and cardiac flutter Repeated ectopic treatment at the same session Having diseases like high blood pressure and hyperactivity

Age

From **11 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

.Patients were randomly assigned to two groups A and B, using Random Allocation software, and compared in two Sequence and two Period (AB, BA)

Blinding (investigator's opinion)

Double blinded

Blinding description

Both drugs are prepared by the researcher using syringes of the same form and size, and the person who prescribes the drug and the person who registers the vital signs are different and are unaware of the contents of the packages.

Placebo

Not used

Assignment

Crossover

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

Isfahan

Postal code

81746-73461

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.MUI.MED.REC.1397.279

Health conditions studied

1

Description of health condition studied

Succinylcholine Chloride

ICD-10 code

T48.1X3

ICD-10 code description

Poisoning by skeletal muscle relaxants [neuromuscular blocking agents], assault

2

Description of health condition studied

cisatracurium

ICD-10 code

T48.1X3

ICD-10 code description

Poisoning by skeletal muscle relaxants [neuromuscular blocking agents], assault

Primary outcomes

1

Description

serum potassium levels

Timepoint

Before the administration of the anesthetic (baseline), before induction of the Electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

potassium test

Secondary outcomes

1

Description

Heart rate changes

Timepoint

Before the administration of the anesthetic (baseline), before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

Heart monitoring

2

Description

Systolic blood pressure

Timepoint

Before the administration of the anesthetic (baseline), before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

Non invasive blood pressure monitor

3

Description

Diastolic blood pressure

Timepoint

Before the administration of the anesthetic (baseline), before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

Non invasive blood pressure monitor

4

Description

Mean arterial pressure

Timepoint

Before the administration of the anesthetic (baseline), before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

Non invasive blood pressure monitor

5

Description

Oxygen saturation

Timepoint

Before the administration of the anesthetic (baseline), before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia

Method of measurement

Percent with pulse oximeter

6

Description

Recovery time

Timepoint

From the end of seizure to full consciousness

Method of measurement

In minutes using a stopwatch

Intervention groups

1

Description

Intervention group: After obtaining a license from the Medical Ethics Committee of Isfahan University of Medical Sciences, patients who are willing to participate in the study. In the first period with the package (b) containing 1.5 mg / kg of ketamine and 50 µg / kg of cis-atracurium and in the second period with the package (a) containing 1.5 mg / kg of ketamine and mg/kg 0.5 of succinylcholine taken under electroshock therapy. And from the right hand, blood samples are taken at the time before administration of the anesthetic drug (baseline) before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia. before induction Anesthesia is provided for patients with a simple oxygen mask and given 4 to 6 liters of oxygen for a period of three minutes. Heart monitoring includes electro-cardiogram and heart rate, pulse oximetry and non-invasive blood pressure for all patients. Heart rate, mean arterial blood pressure, diastolic blood pressure and systolic blood pressure and hemoglobin saturation from oxygen are measured at these times.

Category

Treatment - Drugs

2

Description

Control group: After obtaining a license from the Medical Ethics Committee of Isfahan University of Medical Sciences, patients who are willing to participate in the study. In the first period with the package (a) containing 1.5 mg / kg of ketamine and mg/kg 0.5 of succinylcholine and in the second period with the package (b) containing 1.5 mg / kg of ketamine and 50 µg / kg of cis-atracurium taken under electroshock therapy. And from the right hand, blood samples are taken at the time before administration of the anesthetic drug (baseline) before induction of the electroshock (after administration of the drug), after the seizure, and 20 minutes after induction of anesthesia. before induction Anesthesia is provided for patients with a simple oxygen mask and given 4 to 6 liters of oxygen for a period of three minutes. Heart monitoring includes electro-cardiogram and heart rate, pulse oximetry and non-invasive blood pressure for all patients. Heart rate, mean arterial blood pressure, diastolic blood pressure and systolic blood pressure and hemoglobin saturation from oxygen are measured at these times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Behzad Nazemalroaya

Street address

Soffeh boulevard, Shahid Keshvari 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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8174673461

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research@mui.ac.ir

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

Atefeh Ghosouri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Behzad Nazemalroaya

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Atefeh Ghosouri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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ghosouriatefeh@gmail.com

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

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