Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of changes in blood pressure and heart rate ;following the use of Sodium Thiopental or Ketamine duration and after ECT

Protocol summary

Summary

The purpose of this study: Comparison of changes in blood pressure and heart rate ;following the use of Sodium Thiopental or Ketamine duration and after ECT. Study design:This clinical trial was a randomized double-blind way without controls. Inclusion criteria: patients candidates receiving electroconvulsive therapy seizures; Subjects younger than 25 years old with American society of anesthesiology physical status class 1 (ASAI) . Exclusion criteria: After receiving the shock, hemodynamic unstable.; patients with seizure duration more than 90 seconds less than 20 seconds;After receiving the shock، tracheal intubation indicated; drugs used to react strongly. Sample size:68 patients were divided into two groups of 32. Studied interventions: Ketamine and thiopental was given to another group. Time of intervention: 2015-16. Outcomes studied: In 1st , 5th and 10th minute after seizure blood pressure and heart rate have been measured. After seizure patients got into recovery phase. During this time Apnea have been measured. Patients have been assessed for complications like nausea , vomiting and laryngospasm during recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030726950N1**
Registration date: **2016-06-20, 1395/03/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-20, 1395/03/31

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Isfahan University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of changes in blood pressure and heart rate ;following the use of Sodium Thiopental or Ketamine duration and after ECT

Public title

The effect of the two drugs(Sodium Thiopental or Ketamine) duration and after ECT

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients candidates receiving electroconvulsive therapy seizures; Subjects younger than 25 years old with American society of

anesthesiology physical status class 1 (ASAI) . Exclusion criteria: After receiving the shock, hemodynamic unstable.; patients with seizure duration more than 90 seconds less than 20 seconds;After receiving the shock، tracheal intubation indicated; drugs used to react strongly.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research of Isfahan University Of Medical Sciences

Street address
Vice Chancellor for Research, Building 4, Isfahan University Of Medical Sciences, Hezarjirib St, Isfahan

City
Isfahan

Postal code
7346181746

Approval date
2015-10-25, 1394/08/03

Ethics committee reference number
IR.MUI.REC.94.3.523

Health conditions studied

1

Description of health condition studied
Succinylcholine Chloride

ICD-10 code
T48.1

ICD-10 code description
Poisoning: Skeletal muscle relaxants [neuromuscular blocking agents], Skeletal muscle relaxants [neuromuscular blocking agents]

2

Description of health condition studied
Sodium Thiopental

ICD-10 code
T41.1

ICD-10 code description
Poisoning:Intravenous anaesthetics

3

Description of health condition studied
Ketamine

ICD-10 code
T41.2

ICD-10 code description
Poisoning: Other and unspecified general anaesthetics

Primary outcomes

1

Description
Back to Breathe Spontaneously

Timepoint
From the end of seizure to respiration

Method of measurement
Second with Timer

2

Description
Seizure Duration

Timepoint
From the start to the end of seizure

Method of measurement
Second with Timer

3

Description
Blood Pressure

Timepoint
1, 5 and 10 seconds after the shock

Method of measurement
mmhg with Manometer

4

Description
Pulse

Timepoint
1, 5 and 10 seconds after the shock

Method of measurement
Beat per minute with Pulse Oximeter

5

Description

O2 saturation

Timepoint

1, 5 and 10 seconds after the shock

Method of measurement

Percent with Pulse Oximeter

6

Description

Recovery Duration

Timepoint

From the end of seizure to full consciousness

Method of measurement

Minute with Timer

Secondary outcomes

1

Description

Headache

Timepoint

After recovery

Method of measurement

Ask the patient

2

Description

Cough

Timepoint

After recovery

Method of measurement

Ask the patient

3

Description

Nausea and Vomiting

Timepoint

After recovery

Method of measurement

Ask the patient

4

Description

Laryngospasm

Timepoint

After recovery

Method of measurement

Evaluation of patient such as breathing and o2 sat

5

Description

Muscle Pain

Timepoint

After recovery

Method of measurement

Ask the patient

Intervention groups

1

Description

First group received A packages included succinylcholine (0.5 mg/kg) and Sodium thiopental (2 mg/kg).Drugs inject IV and bolusly.

Category

Treatment - Drugs

2

Description

Second group received B packages included succinylcholine (0.5 mg/kg) and Ketamine (1mg/kg).Drugs inject IV and bolusly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Psychiatric Ward of Medical Center Al-Zahra

Full name of responsible person

Dr. Behzad Nazemroaya

Street address

Medical Center Al-Zahra, Blvd Sofeh, Shahid Keshvari Highway, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Isfahan University Of Medical Sciences

Full name of responsible person

Research Vicar

Street address

Vice Chancellor for Research, Building4, Isfahan University Of Medical Sciences, Hezarjirib St.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Isfahan University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Anesthesiology
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Position
Assistant Professor/Faculty
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty