

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 (ASA1) . 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

Country

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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 (ASA1) . 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

Full name of responsible person

Dr. Behzad Nazemroaya

Position

Assistant Professor/Faculty

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Web page address**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*