

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative evaluation of midazolam effects before and after seizure occurrence on post ECT complications in teenagers

Protocol summary

Study aim

Evaluating midazolam effect before and after seizure occurrence on post ECT complications

Design

This study is a parallel randomised double-blind clinical trial designed and performed on 69 patients which is currently in phase 3.

Settings and conduct

This study is a double blinded clinical trial designed and performed in Alzahra hospital on patients with 13 to 19 years of age. Patients will be randomly divided into 3 groups and they will be receiving the drug packages. Care providers who are responsible for drug injection and care providers who are responsible for monitoring the patients are completely unaware of the content of the packages. Patients will be monitored for blood pressure, oxygen saturation, pulse rate and electrocardiogram while they are receiving ECT and 5,10 and 15 minutes after that. After the patients are completely conscious they will be evaluated based on nausea, muscle pain and headache

Participants/Inclusion and exclusion criteria

The inclusion criteria include 6 to 18 years of age, having indications for ECT, written consent from parents, npo regimen ASA I&II and the exclusion criteria include patients who do not have a stable hemodynamic status and patients who are diagnosed with major diseases like asthma, drug allergies ,neuromuscular diseases, epilepsy, hypertension and cardiovascular diseases.

Intervention groups

Patients will be randomly divided into 3 groups: group A which receives midazolam with the routine drug regimen before ECT , group B which receives midazolam after ECT and group c which is considered as the control group and receives the routine drug regimen without midazolam.

Main outcome variables

Muscle pain, headache, nausea, tachycardia, bradycardia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N16**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

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

Expected recruitment start date

2020-02-15, 1398/11/26

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of midazolam effects before and after seizure occurrence on post ECT complications in teenagers

Public title

Evaluating Midazolam effect on post ECT complications in teenagers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

13 to 18 years of age ASA I&II Having indications for ECT
Written consent from parents NPO regimen

Exclusion criteria:

Patients who do not have a stable Hemodynamic status
Patients with major diseases like asthma, drug allergy, neuromuscular diseases ,epilepsy, hypertension and cardiovascular diseases

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be randomly divided into three groups by using computer software and closed envelope technique. The intervention groups will receive midazolam before and after ECT and the group receiving the routine treatments and placebo without midazolam will be considered as the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be randomly divided into 3 groups by using computer software and each one of the groups will be receiving one of the 3 drug packages (package A & B & C (placebo)). drugs of three packages 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 finally the investigator deciphers the codes after data analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of medical sciences

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Hezar jarib street

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Postal code

81746-73461

Approval date

2020-02-15, 1398/11/26

Ethics committee reference number

IR.MUI.MED.REC.1398.587

Health conditions studied**1****Description of health condition studied**

electroconvulsive therapy complications

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

tachycardia - bradycardia

Timepoint

0 , 5 , 10 , 15 minutes after ECT

Method of measurement

heart monitoring device

2**Description**

headache

Timepoint

immediately after full consciousness , every 15 minutes in first hour then every 2 hours until 6 hours

Method of measurement

questionnaire

3**Description**

myalgia

Timepoint

immediately after full consciousness , every 15 minutes in first hour then every 2 hours to 6 hour

Method of measurement

questionnaire

4

Description

nausea

Timepoint

immediately after full consciousness , every 15 minutes in first hour then every 2 hours to 6 hour

Method of measurement

questionnaire

5

Description

o2 saturation

Timepoint

before injection of drug , during seizure and 5, 10 , 15 minutes after ECT

Method of measurement

pulse oxymetry

6

Description

systolic and diastolic blood pressure

Timepoint

before drug injection, during seizures and after seizures

Method of measurement

Non invasive blood pressure monitor

7

Description

mean blood pressure

Timepoint

before drug injection, during seizures and after seizures

Method of measurement

Non invasive blood pressure monitor

8

Description

recovery time

Timepoint

From the end of seizure to full consciousness

Method of measurement

in minutes using a chornometer

9

Description

specific complications such as hypoxia and respiratory depression

Timepoint

From the end of seizure to full consciousness

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group A which receives package A consisted of routine anesthesia medications (sodium thiopental with a dose of 2 mg/kg and 0.5 mg/kg of succinyl choline) plus 1 mg of midazolam before inducing the seizure and administration of anesthesia drugs and 1 cc of N/S after ECT is done.

Category

Treatment - Drugs

2

Description

Intervention group: group B which receives package B consisted of the routine anesthesua medication mentioned above and 1 cc of N/S before inducing seizures and 1 mg of midazolam after the ECT is done and the seizure are completely over.

Category

Treatment - Drugs

3

Description

Control group: group C which receives 1 cc of N/S before inducing seizures and after the ECT is done as a placebo in addition to the routine anesthesia medications mentioned above.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad nazemroaya

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Sponsors / Funding sources

Sponsor**Name of organization / entity**

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Full name of responsible personVice Chancellor for Research of Isfahan University Of
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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

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

Maryam Raisi

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

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Specialist

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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**

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