Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 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

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Iran (Islamic Republic of)

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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 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 dara 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

Street address
Hezar jarib street

City
Esfahan

Province
Isfehan

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 oxymetery

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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Medical Center Al-Zahra, Blvd Sofeh, Shahid Keshvari Highway
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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
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
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Esfahan University of Medical Sciences
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Person responsible for updating data

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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