Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the Effects of Low-Dose Midazolam and Low-Dose etomidate on Prevention of Etomidate-Induced Myoclonus in electroconvulsive therapy

Protocol summary

Study aim
Comparison of low dose midazolam and etomidate for the Prevention of Myoclonic Movements following general anesthesia with etomidate Injection in Electroconvulsive Therapy.

Design
This study was conducted in parallel, double-blind, randomized, 120 people who were in the Phase 3 trial were designed.

Settings and conduct
After the etomidate injection, the intensity of myoclonus was graded clinically according to the following scale for a period of 2 min: 0, no myoclonus; 1,short movement of a body segment e.g. a finger or a wrist, 2 mild movements of two different muscles or 3, intense clonic movements in two or more muscle groups, fast adduction of a limb.

Participants/Inclusion and exclusion criteria
Inclusion criteria:120 Patients candided ECT; ASAI and ASA II; Age aged 9 to 15 years. exclusion criteria: severe cardiovascular disease; Kidney disease; liver disease; chronic respiratory disease; intubated; drug reaction

Intervention groups
For all intervention groups, informed consent is obtained from the parents of patients. Then an appropriate peripheral vein is taken from the patients and the blood pressure and electrocardiography and pulse oximetry devices are connected to the patients, and all patients undergoing general anesthetic induction with an autoimmune dose of 0.15 mg/kg. Intervention group A: we prescribe normal saline or 1 cc Intervention group B: we prescribe midazolam or 0.15 mg/kg Intervention group C: we prescribe etomidate of 0.03 mg/kg

Main outcome variables
Myoclonus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N6**
Registration date: **2018-07-03, 1397/04/12**
Registration timing: **retrospective**

Last update: **2018-07-03, 1397/04/12**
Update count: **0**

Registration date
2018-07-03, 1397/04/12

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
2017-06-22, 1396/04/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the Effects of Low-Dose Midazolam and Low-Dose etomidate on Prevention of Etomidate-Induced Myoclonus in electroconvulsive therapy

Public title
Comparison of low dose midazolam and etomidate for the Prevention of myoclonic Movements following etomidate Injection.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All Patients candidate Electroconvulsive Therapy ASA I,ASAII Age 6 - 15 years

Exclusion criteria:
Severe cardiovascular disease kidney disease Liver disease Chronic respiratory disease drugs Allergy discontinue of cooperation intubation

Age
From **9 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to three groups A, B, C, using the Random Allocation computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
All drugs are in one form and in the form of a volume in the syringe by the researcher, and the hemodynamic changes are monitored and recorded, so the attending and the clinical caregiver and the evaluator do not understand the type of medication.

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
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-05-25, 1396/03/04

Ethics committee reference number
IR.MUI.REC.1396.3.442

Health conditions studied

1

Description of health condition studied
Myoclonic Movements

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Myoclonus

Timepoint
After induction anesthesia

Method of measurement
Observation of myoclonic movements (0,1,2,3)

2

Description
Heart rate changes

Timepoint
Before the intervention, then after the intervention, , 5, 10, 20 minutes after intervention and then After The discharge time of recovery

Method of measurement
Pulse oximetry device

3

Description
Mean arterial blood pressure

Timepoint
Before the intervention, then after the intervention, , 5, 10, 20 minutes after intervention and then After The discharge time of recovery

Method of measurement
non invasive blood pressure

4

Description
Oxygen saturation

Timepoint
Before the intervention, then after the intervention, , 5, 10, 20 minutes after intervention and then After The discharge time of recovery
Method of measurement
Pulse oximetry device

5

Description
Duration of seizure
Timepoint
After intervention
Method of measurement
In seconds using a chronometer

6

Description
Recovery Duration
Timepoint
Since entering the recovery section until discharge time
Method of measurement
Minute with using a chronometer

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
During the stay in the recovery
Method of measurement
In minutes using the chronometer

2

Description
Headache
Timepoint
During the stay in the recovery
Method of measurement
Ask the patient about this complication

3

Description
Muscle Pain
Timepoint
During the stay in the recovery
Method of measurement
Ask the patient about this complication

Intervention groups

1

Description
Intervention group:
Category
Prevention

2

Description
Intervention group:
Category
Prevention

3

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahara hospital
Full name of responsible person
Behzad Nazemroaya
Street address
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Sponsors / Funding sources

1

Sponsor
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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
Seyedeh Maryam Mousavi
Position
Medical student/ Intern
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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