

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; ASA I 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

Isfahan

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

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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

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Person responsible for general inquiries

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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