Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the effect of midazolam on the incidence of restlessness and agitation in patients undergoing electroshock therapy at 5 Azar Hospital in Gorgan in 2023

Protocol summary

Study aim

Determining the effect of midazolam administration on the incidence of restlessness and agitation in patients immediately and one hour after electroshock therapy.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. For randomization, a list of random numbers was used from the Randomization.com website.

Settings and conduct

Psychiatry Department of 5 Azar Medical Education Center in Gorgan City.

Participants/Inclusion and exclusion criteria

- The consent of the patient or his legal guardian The patient diagnosed with psychosis is indicated for Electroconvulsive therapy (ECT) - Age range 18-75 years - Patient's satisfaction to conduct research Exclusion Criteria: - Allergy to any of the anesthetic drugs - Creating hemodynamic changes or less than 20 requiring intervention - The need for more anesthetic drugs for patient induction - Having a history of malignant hyperthermia and a family history -Suffering from cardiovascular diseases without compensation - Known cases of chronic respiratory disease - Clear history of liver and kidney disease - History of Myocardial infarction (MI) less than 6 months - Presence of high intracranial pressure (ICP) - Having a brain tumor - Known cases of cerebrovascular problems (such as aneurysm)

Intervention groups

This study group has the same entry characteristics as the control group, with the difference that in order to perform electroshock therapy, midazolam is administered at the rate of 0.02-0.01 mg/kg in 3-4 minutes before intravenous atropine injection to the patient. It is injected and, like the control group, 2 mg/kg of nesdonal and 0.5 mg/kg of succinylcholine are used for induction and relaxation. The only difference between these two groups is the intravenous injection of midazolam.

Main outcome variables

Agitation and restlessness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170108031818N3**
Registration date: **2023-01-23, 1401/11/03**
Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**
Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

fatemeh mehravar

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of midazolam on the incidence of restlessness and agitation in patients undergoing electroshock therapy at 5 Azar Hospital in Gorgan in 2023

Public title
The effect of midazolam drug on the occurrence of restlessness and agitation in patients undergoing electroshock therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient diagnosed with psychosis is indicated for ECT
Exclusion criteria:
Age range 18-75 years Patient satisfaction to conduct research
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
By referring to the Randomization.com website and using the block of four method, a list of random numbers will be generated by a member of the research team, who is the only one who knows about the process of entering the groups (sample size of 50 people, in two Group A – B). Then the letters A-B will be written on the cards and placed in thick numbered envelopes (1 to 50). After checking the entry criteria, the participating people will receive the respective envelopes in the order of entry into the study and their allocation status will be determined into two groups of intervention (A) and comparison (B) according to the cards in the envelopes. It is obvious that the sequence of entering the groups will be kept secret until the start of the intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
At first, two separate groups are considered group A (midazolam group) and group B (placebo). Groups A and B are randomly selected for each person and every visit for electroshock therapy by the anesthesiologist (who is aware of the drug content). It is not group A or B) and is injected by him. In this case, each person may randomly receive midazolam in four times of his injection, for example, he may be in group A (or he may not receive it) or group B. It should be said that the number of questionnaires A and B and the prepared drugs are equal. Neither the anesthesiologist, nor the attending resident, nor the anesthetist, nor the two attending nurses know about the content of midazolam or distilled water. Only an anesthesiologist who prepares the drugs from the operating room He is aware of the drugs and delivers the drugs to the electroshock therapy environment and leaves the environment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
Shasat Kala Street
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Gorgan
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Golestan
Postal code
4915789465
Approval date
2022-12-11, 1401/09/20
Ethics committee reference number
ir.goums.rec.1401.454

Health conditions studied

1

Description of health condition studied
Patients undergoing electroshock therapy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Restlessness and agitation
Timepoint
Twice a day at 8-10 and 16-18 for a maximum of 4 days
Method of measurement

The Richmond Agitation and Sedation Scale (RASS)

Secondary outcomes

1

Description
Cardiovascular response of trauma patients in special surgery departments
Timepoint
Before and after each drug intervention
Method of measurement
Blood pressure with a blood pressure monitor device and the patient's pulse with a heart and breathing monitor with a manual counter in one minute.

Intervention groups

1

Description
For the intervention group, before the induction of anesthesia, hemodynamic symptoms are measured before anesthesia, and the patient is preoxygenated. Then midazolam drug at the rate of 0.01-0.02 mg/kg in 3 to 4 minutes before intravenous atropine injection. It is injected into the patient to prevent the parasympathetic side effects caused by the electric shock, then 2 mg per Kg of nesdonal is used for induction of anesthesia, and 0.5 mg/kg of succinylcholine is used to create muscle relaxation. Then the electric shock is performed by a neurologist. During the electric shock, a sponge Y piece is used in the patient's mouth to protect the patient's airway during tonic and clonic convulsions and to protect the patient's teeth from stiffness caused by Do not break the contraction. After the convulsions end, the patient is suctioned through the mouth and oxygen therapy is performed so that the patient returns to spontaneous breathing.
Category
Treatment - Drugs

2

Description
Control group: the anesthesiologist preoxygenates the patient before the induction of anesthesia and injects two cc of distilled water from a syringe without knowing the contents of the syringe, then 3 to 4 minutes later, 0.5 mg of atropine is administered intravenously. to prevent the parasympathetic side effects caused by the electric shock, then 2 mg/kg of nesdonal is used for induction of anesthesia and 0.5 mg/kg of succinylcholine is used to induce muscle relaxation, then the electric shock is administered by a neurologist. It is done, during the electric shock in the patient's mouth, the Y sponge piece is used to protect the patient's airway during the tonic and clonic convulsions and prevent the patient's teeth from breaking due to the stiffness caused by the contraction. After the convulsions end. , the patient is suctioned through the mouth and oxygen therapy is performed so that the patient returns to spontaneous breathing."
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5 Azar Hospital, Gorgan
Full name of responsible person
Dr. seyed Mahrokh alinaghi Maddah
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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
Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Seyed Maherukh Madah

Position

Associate professor

Latest degree

Specialist

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available