Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the Effect of Propofol-Dexmedetomidine versus Propofol in Anesthesia Induction in Patients with Major Depression or Bipolar-Disorder under Electroconvulsive therapy

Protocol summary

Study aim

The purpose of this research is to investigate the propofol-dexmedetomidine in comparison with propofol in induction of anesthesia in patients with major depression or bipolar disorder for electroconvulsive therapy.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 per 82 patients. Random computer- generated numbers will be used for randomization.

Settings and conduct

Effects of propofol-dexmedetomidine in induction of anesthesia in patients with major depression or bipolar disorder who referred to Qods Hospital in Sanandaj for electroconvulsive therapy. After dividing the patients by computer random number generation, intervention group 1 patients received propofol 1 mg/kg along with 0.5 µg/kg dexmedetomidine and intervention group 2 patients received propofol 1 mg/kg. For blinding, the patient and evaluator is not aware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age 18 to 50 years, 2. Patient in ASA class 1 or 2 physical status, 3. A patient diagnosed with major depression or bipolar disorder referred by a psychiatrist. Exclusion Criteria: 1. History of cardiovascular, kidney, liver and lung disease 2. History of other mental diseases, except major depression or bipolar disorder 3. History of head trauma 4. History of cardiovascular surgery 5. History of allergy to propofol or foods such as eggs or soybeans 6. Patients under treatment with bupropion and anticonvulsant 7. The doctor's lack of consent for the patient's participation in the study

Intervention groups

Patients in the group 2, receiving propofol at a dose of 1 mg/kg plus, 0.5 µg/kg of dexmedetomidine. Patients in the group 2 receiving propofol at a dose of 1 mg/kg.

Main outcome variables

-Seizure duration - Recovery time - Mean arterial pressure - Sedation/Agitation score in recovery Pain score in recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231009059668N1**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Fatemeh Karimkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 7228

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-12-22, 1402/10/01

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

Scientific title
Comparing the Effect of Propofol-Dexmedetomidine versus Propofol in Anesthesia Induction in Patients with Major Depression or Bipolar-Disorder under Electroconvulsive therapy

Public title
Effect of Propofol-Dexmedetomidine in Anesthesia Induction in Patients with Major Depression or Bipolar-Disorder under Electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years Patient in class 1 or 2 ASA physical status Patient diagnosed with major depression or bipolar disorder referred by a psychiatrist
Exclusion criteria:
History of cardiovascular, kidney, liver and lung disease History of other mental diseases, except major depression or bipolar disorder History of head trauma History of cardiovascular surgery History of allergy to propofol or foods such as eggs or soybeans Patient under treatment with bupropion and anticonvulsant The attending physician's lack of consent for the patient's participation in the study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done randomly using computer generated random numbers. Thus, each "odd number" produced belongs to group 1 (intervention group) and each randomly generated "even number" belongs to group 2 (patient placement in the control group)
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind this study, patients do not know which study groups they are in. Also, the prepared medication (dexmedetomidine- propofol OR propofol), in the same volume and appearance, is prepared and coded by an anesthesia nurse who is not present in the study. The anesthesiologist who also performs the procedure is not aware of the prescription medication and the grouping of patients. Patients will be evaluated by an anesthesia resident who is not aware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Kurdistan University of Medical Sciences
Street address
Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6617913446
Approval date
2022-01-25, 1400/11/05
Ethics committee reference number
IR.MUK.REC.1400.273

Health conditions studied

1

Description of health condition studied
Bipolar disorders
ICD-10 code
F31
ICD-10 code description
Bipolar disorder

2

Description of health condition studied
Major depression
ICD-10 code
F33
ICD-10 code description
Major depressive disorder, recurrent

Primary outcomes

1

Description
Seizure duration

Timepoint
The end of the discharge time of the electric shock until the completion of all visible movements in all parts of the body
Method of measurement
Timer (seconds)

2

Description
Recovery time
Timepoint
From the end of the injection of succinylcholine to the return of breathing and opening the eyes and following the instructions completely correctly by the patients
Method of measurement
Timer (minutes)

3

Description
Hemodynamic changes (mean arterial pressure, heart rate)
Timepoint
Before induction of anesthesia, during discharge of electric shock, 5, 10 and 15 minutes after discharge of electric shock
Method of measurement
Using a portable automatic monitoring (mean arterial pressure in mmHg and heart rate in beats per minute)

Secondary outcomes

1

Description
Pain
Timepoint
In 5, 10 and 15 minutes after the end of the electric shock discharge and also the recovery time
Method of measurement
Visual Analogue Scale

2

Description
Sedation and agitation
Timepoint
In 5, 10 and 15 minutes after the end of the electric shock discharge and also the recovery time
Method of measurement
Sedation-Agitation Scale

Intervention groups

1

Description
Intervention group: Administration of propofol at a dose of 1 mg/kg along with receiving 0.5 µg/kg of dexmedetomidine to induce anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group: administration of propofol at a dose of 1 mg/kg to induce anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods hospital in Sanandaj
Full name of responsible person
Negin Ghadami
Street address
Pasdaran Blvd - Entezam Blvd
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Web page address
https://muk.ac.ir/Page?pageId=45

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
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Pasdaran Blvd
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6617713446
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Email
Research@muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Negin Ghadami
Position
Assisstant professor
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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
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