

# 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

##### Email address

dr.fatemehkarimkhani@gmail.com

##### 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

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

6617713141

#### **Phone**

+98 87 3366 0025

#### **Email**

qodshospital.sanandaj@gmail.com

#### **Web page address**

<https://muk.ac.ir/Page?pagelId=45>

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Sanandaj University of Medical Sciences

#### **Full name of responsible person**

Afshin Maleki

#### **Street address**

Pasdaran Blvd

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

6617713446

#### **Phone**

+98 87 3366 4654

#### **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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Pasdaran Blvd

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3362 7228

**Email**

ghadaminegin@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Negin Ghadami

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Pasdaran Blvd

**City**

Sanandaj

**Province**

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**Postal code**

6617713446

**Phone**

+98 87 3362 7228

**Email**

ghadaminegin@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Fatemeh Karimkhani

**Position**

Resident of Anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Pasdaran Blvd

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3362 7228

**Fax****Email**

dr.fatemehkarimkhani@gmail.com

**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