

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison the effect of adjuvant Remifentanyl, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

#### Protocol summary

##### Study aim

Comparison the effect of adjuvant Remifentanyl, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

##### Design

The study will be double blind and clinical trial.90 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3.

##### Settings and conduct

patients with major depressive disorder candidates for electroconvulsive therapy in Amirkabir Hospital in Arak are divided into 3 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with major depressive disorder are candidates for ETC, consent to participate in the study, 18 to 60 years, body mass index 20 to 30, no history of underlying heart, lung, kidney and liver diseases, no history of recent CVA or MI, insensitivity to drugs Exclusion criteria: all patients who experience cardiorespiratory arrest during ECT, all patients who need intubation after ECT due to prolonged apnea and respiratory failure, all patients who do not experience sufficient and desired seizures during ECT, all patients who want to withdraw from the study or do not want to continue electroshock therapy

##### Intervention groups

Intervention group 1: Before induction of anesthesia, 100 micrograms of Remifentanyl is injected intravenously. Intervention group 2: Before the induction of anesthesia, intravenous injection of 0.5 mg/kg Dexmethomidine is performed. Intervention group 3: After induction of anesthesia as mentioned above, immediately before stimulation with ECT, an amount of 2.5 mg Metoral is

injected .

##### Main outcome variables

Average blood pressure, average heart rate, average percentage of oxygen saturation, patient satisfaction, agitation, seizure duration, recovery period

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N178**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **prospective**

Last update: **2022-12-31, 1401/10/10**

Update count: **0**

##### Registration date

2022-12-31, 1401/10/10

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-20, 1401/10/30

##### Expected recruitment end date

2024-01-20, 1402/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparision the effect of adjuvant Remifentanil, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

**Public title**

Comparision the effect of adjuvant Remifentanil, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients with major depressive disorder are candidates for ETC Consent to participate in the study 18 to 60 years Body mass index 20 to 30 Patients with major depressive disorder who do not have other psychiatric illnesses at the same time. No history of underlying heart, lung, kidney and liver diseases No history of recent CVA or MI Insensitivity to Remifentanil or Dex Medtomidine or Metoral or Thiopental All patients who are indicated to receive ECT according to psychiatric treatment criteria. Absence of pregnancy and breastfeeding

**Exclusion criteria:**

All patients who experience cardiorespiratory arrest during ECT. All patients who need intubation after ECT due to prolonged apnea and respiratory failure All patients who do not experience sufficient and desired seizures during ECT. All patients who want to withdraw from the study or do not want to continue electroshock therapy.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 3 and 6. Random sequence will be generated by an epidemiologist by running an online program in

sealed envelope website

(<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Blinding is carried out in such a way that after obtaining the informed consent of the patients to participate in the study, using the randomized block method, the patients are completely randomly assigned to three equal groups of remifentanil and thiopental (group A) and dexmedomidine by the anesthesiologist. and thiopental (group B) and Metoral and thiopental (group C) are divided. Then, the drugs are prepared in advance by the anesthesiologist in charge of the plan and given to the fellow anesthesia resident who does not know the type of drugs. In all three drug groups that are used for the intervention (remifentanil-thiopental, dexmedomidine-thiopental, and metoral-thiopental), the syringes are of the same shape, and the volume of the injected drug is adjusted to CC5 in order to comply with the blinding. Also, the intern in charge of the project did not know the type of study groups from the beginning, and only after ECT induction for the patients, he is responsible for filling the questionnaires of the project, and therefore, he is not aware of the type of study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee Of Arak University Of Medical Sciences

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

848176941

**Approval date**

2022-10-09, 1401/07/17

**Ethics committee reference number**

IR.ARAKMU.REC.1401.206

**Health conditions studied**

## 1

### **Description of health condition studied**

major depressive disorder candidates for electroconvulsive therapy

### **ICD-10 code**

F06.32

### **ICD-10 code description**

Mood disorder due to known physiological condition with major depressive-like episode

## **Primary outcomes**

## 1

### **Description**

Average blood pressure

### **Timepoint**

Recovery

### **Method of measurement**

Barometer

## 2

### **Description**

Average heart rate

### **Timepoint**

Recovery

### **Method of measurement**

Pulse oximeter

## 3

### **Description**

Average percentage of oxygen saturation,

### **Timepoint**

Recovery

### **Method of measurement**

Pulse oximeter

## 4

### **Description**

Patient satisfaction

### **Timepoint**

Recovery

### **Method of measurement**

Question

## 5

### **Description**

Agitation

### **Timepoint**

Recovery

### **Method of measurement**

Physical examination

## 6

### **Description**

Seizure duration

### **Timepoint**

Recovery

### **Method of measurement**

Observation

## 7

### **Description**

Recovery period

### **Timepoint**

Recovery

### **Method of measurement**

Observation

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group1: Before induction of anesthesia, 100 micrograms of remifentanyl is injected intravenously

### **Category**

Treatment - Drugs

## 2

### **Description**

Intervention group 2: Before the induction of anesthesia, intravenous injection of 0.5 mg/kg dex methomidine is performed.

### **Category**

Treatment - Drugs

## 3

### **Description**

Intervention group 3: After induction of anesthesia as mentioned above, immediately before stimulation with ECT, an amount of 2.5 mg Metoral is injected .

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Amirkabir hospital

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

Dr HALireza Kamali

#### **Street address**

Amirkabir hospital, Parastar square, Arak

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

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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**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Anita Alaghemand

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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