

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

#### Protocol summary

##### Study aim

Aim of this study is comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

##### Design

Patients with mood disorder candidate ECT referring Amirkabir hospital. This study is clinical trial and double blind. 48 patients is in this study.

##### Settings and conduct

Patients with mood disorder candidate ECT referring Amirkabir hospital. This study is clinical trial and double blind. 48 patients is in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with cognitive dysfunction receive ECT, 18 to 60 years Exclusion criteria: All patients with anesthesia induced cardiac arrest during ECT, all patients who after ECT due to long-term apnea and respiratory distress need to intubation, all patients who don't have seizures during the ECT process.

##### Intervention groups

We inject 0/5 micro gram in kilogram Dexmedetomidin before intubation in first group and we inject 2/5 milligram Metoprolol 10 minute before intubation.

##### Main outcome variables

Mean of blood pressure, Heart rate, degree of restlessness, degree of satisfaction, duration of seizure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N87**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

##### Registration date

2018-10-31, 1397/08/09

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-20, 1397/02/30

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

##### Public title

Comparison effect of addition Dexmedetomidine and

Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

All patients with cognitive dysfunction receive ECT 18 to 60 years

##### **Exclusion criteria:**

All patients with anesthesia induced cardiac arrest during ECT All patients who after ECT due to long-term apnea and respiratory distress need to intubation. All patients who don't have seizures during the ECT process.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

- Outcome assessor
- Data analyser

#### **Sample size**

Target sample size: **48**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Simple randomization with random numbers

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

This study is double blind.Outcome evaluator and analyzer are blind (double blind).Outcome evaluator and analyzer don't aware from grouping.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee 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**

2018-05-13, 1397/02/23

#### **Ethics committee reference number**

IR.ARAKMU.REC.1397.044

## **Health conditions studied**

### **1**

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

Mood disorder

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

F06.3

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

Mood disorder due to known physiological condition

## **Primary outcomes**

### **1**

#### **Description**

Mean of blood pressure

#### **Timepoint**

Before and after electro convulsive therapy

#### **Method of measurement**

Barometer

### **2**

#### **Description**

Heart rate

#### **Timepoint**

Before and after electro convulsive therapy

#### **Method of measurement**

count

### **3**

#### **Description**

Degree of restlessness

#### **Timepoint**

After electro convulsive therapy

#### **Method of measurement**

Agitation score

### **4**

#### **Description**

Degree of satisfaction

#### **Timepoint**

After electro convulsive therapy

#### **Method of measurement**

satisfaction score

### **5**

#### **Description**

Duration of seizure

#### **Timepoint**

After electro convulsive therapy

#### **Method of measurement**

Minute

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: We inject 0/5 micro gram in kilogram Dexmedetomidin before intubation in first group.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: We inject 2/5 milligram Metoral 10 minute before intubation.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkabir hospital

##### Full name of responsible person

Dr Hamidreza Jamilian

##### Street address

Amirkabir hospital, Parastar Square

##### City

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##### Province

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##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Fax

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##### Email

hjamilian@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

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

##### City

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#### Postal code

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#### Phone

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#### Email

m.arjmandzadegan@arak.mu.ac.ir

#### 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 Alireza Kamali

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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alikalamiir@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Hamidreza Jamilian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

researcher in university

**Under which criteria data/document could be used**

If there are additional questions

**From where data/document is obtainable**

Dr Hamidreza Jamilian

**What processes are involved for a request to access data/document**

They have to write letters to the professors and the university

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Talat Mohammadi

**Position**

Resident of psychology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht

**City**

Arak